S. HRG. 107–321

NUCLEAR REGULATORY COMMISSION: FISCAL YEAR 2002 PROGRAMS

HEARING

BEFORE THE

SUBCOMMITTEE ON CLEAN AIR, WETLANDS, PRIVATE PROPERTY, AND NUCLEAR SAFETY

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON

OVERSIGHT OF THE PROGRAMS OF THE U.S. NUCLEAR REGULATORY COMMISSION FOR FISCAL YEAR 2002

MAY 8, 2001

Printed for the use of the Committee on Environment and Public Works

U.S. GOVERNMENT PRINTING OFFICE
78–072 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
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C O N T E N T S

NUCLEAR REGULATORY COMMISSION: FISCAL YEAR 2002 PROGRAMS

TUESDAY, MAY 8, 2001

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON CLEAN AIR, WETLANDS,
PRIVATE PROPERTY, AND NUCLEAR SAFETY,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m. in room 628, Senate Dirksen Building, Hon. George V. Voinovich (chairman of the subcommittee) presiding.

Present: Senators Voinovich, Inhofe, Corzine, Carper, and Reid.

OPENING STATEMENT OF HON. GEORGE V. VOINOVICH, U.S. SENATOR FROM THE STATE OF OHIO

Senator VOINOVICH. The hearing will come to order. Good morning.

Today's hearing continues our ongoing oversight of the Nuclear Regulatory Commission. Now, this oversight began by my predecessor, Senator Jim Inhofe, in 1998, and it is the fourth oversight hearing in the last 4 years. I think Senator Inhofe deserves a lot of credit for helping to turn the regulatory process around at the NRC.

Everyone I've met this year credits you, Senator Inhofe, for your oversight hearings and for the change to the risk-based regulations at the NRC and for focusing the NRC on processing relicense applications quickly.

It's amazing. Everywhere I go they brag about Jim and what he's done. I think that it's nice that people recognize the contribution that you have made.

These changes at the NRC have helped create new interest in nuclear energy, including the first discussions in years about building new nuclear facilities. It is my intention as chairman to continue this strong oversight to ensure that nuclear energy remains a viable energy option and an important part of our national fuel mix.

Over the last 40 years, nuclear energy has proven to be a safe, reliable, and clean source of energy. It currently produces 20 percent of our electricity, and since 1973 nuclear energy has avoided over 62 million tons of sulfur dioxide, over 32 million tons of nitrogen, and over 2.6 billion tons of carbon, which would have been released by fossil fuel plants producing the same amount of electricity.

While the United States is 20 percent dependent on nuclear energy, we are falling behind worldwide. France is 76 percent dependent on nuclear energy, and Japan is approximately 50 percent reliant on nuclear energy.

The Energy Information Administration predicts that we will need about a 30 percent increase in electrical generation by the year 2015. Currently, we are dependent on fossil fuels, coal, oil, gas, and will be for the conceivable future. Nuclear is and will be the next best alternative. Together, solar and wind provides less than 1/10 of 1 percent of U.S. energy needs, and I've heard some of my colleagues talking about the wind and the sun and the water, but the fact of the matter is that the demand for energy in this country cannot be satisfied with what I just talked about. That doesn't mean that we shouldn't be moving forward on all of that in alternative sources of energy, but the fact is we're going to need to produce more energy in this country and it's going to be a while before some of these other ideas that folks have are going to be able to get to a point where it's going to make a real dent on that demand.

If we're serious about protecting our environment and providing safe, reliable, and affordable electricity to all Americans, we need to improve how we burn fossil fuels, promote efficiency, and increase the development of nuclear energy for today and the foreseeable future. We also need to continue investing in renewables, as I said, such as solar and wind to make them cost effective and feasible, not for today or tomorrow but for use at some point in the future.

In order to continue to rely on nuclear energy and increase its use, the NRC must accomplish the following:

No. 1, most important is public safety. Nuclear power has a great safety record and we must continue to improve upon it.

No. 2, we must do everything we can about the human capital crisis affecting the nuclear industry. At the NRC, for every employee under the age of 30, there are six employees over the age of 60. The private industry and the nuclear Navy are having similar problems, so we've got a problem right across the board in terms of nuclear engineering.

No. 3, the NRC must continue examining the relicensing process. The first two renewals occurred on schedule. The NRC must examine the procedures to make sure they can process multiple applications at the same time.

No. 4, the NRC must continue to improve the regulatory certainty. Over the last few years, the NRC has made progress in delivering certainty to the enforcement and regulatory area through the risk-based approach. That needs to continue.

No. 5, the NRC must address how we can get more nuclear generation. Can existing facilities increase generation? Is that possible? What can the Government do to encourage the building of new nuclear units?

No. 6, how do we address the waste issue? The Federal Government has a legal and moral obligation to solve the waste issue as quickly as possible. Nuclear ratepayers across the country have paid $15.8 billion—that's $15.8 billion—in additional taxes to the U.S. Government for the building of a high-level waste storage fa-

cility. We must stop the politics on this issue and get it resolved, and hopefully that will happen by the end of this year.

I hope to examine these issues in today's hearings, but we will continue to examine these issues in the weeks and months to come. In addition to today's hearings, we will have another hearing addressing nuclear radiation standards. This is an important issue, as we discuss possible storage at Yucca Mountain, the decommissioning of facilities, and the potential contact people will have with radiation sources.

I am a cosponsor of the Murkowski energy policy bill, Senate 388, and I am examining the nuclear provisions of that legislation. Since the Nuclear Regulatory Commission falls under the jurisdiction of this subcommittee, I will be introducing my own legislation to complement Senator Murkowski's to encourage and expand the safe use of nuclear energy. I happen to believe that we need to get going in terms of producing more energy in this country. The public has to know that there's going to be some light at the end of the tunnel, and it seems to me we've got to get moving as quickly with some of this legislation as we can.

Senator Inhofe, we may just have to pull out a couple of these pieces of it and fast track them before we do the whole watermelon as being conceived right now by the Vice President and Murkowski and—this place runs very slowly.

[Laughter.]

Senator VOINOVICH. And the public needs to know, you know, that we've got a problem in the country right now, and energy costs are one of the reasons why we are having a funk in the economy today, and people have got to believe that things are going to get better.

Our witnesses today include a broad spectrum of viewpoints—the chairman and commissioners of the NRC industry, public interest, the GAO, and a Wall Street analyst. I look forward to their testimony and working with my colleagues on these issues.

I will now call on Senator Inhofe for his opening statement.

Senator Inhofe.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE. Thank you, Mr. Chairman.

I endorse everything that you said. In fact, my opening statement included a lot of the same things, perhaps stated a little bit differently. And I appreciate your compliments, but I think that each one of the commissioners at this table would agree that any bureaucracy—and, of course, NRC is a bureaucracy—that goes without any oversight hearings for a period of 10 years, that it does tend to get a little sloppy. And we've talked about this and we've seen some very good improvements. I compliment the first panel for some of the changes they have made.

Last week, the Environmental Committee had a hearing on the science of global climate change and issues related to reducing net greenhouse gas emissions. In that hearing, I outlined my strong support for expanding the nuclear energy, as I have for many years. With nuclear energy, our Nation wins on many levels. We have an inexpensive and reliable source of energy. Increased nu-

clear capacity will contribute to more stable energy prices. This is one of the problems that we've had is the unpredictability that's out there.

As the Nation takes steps to increase our nuclear capacity, we'll put our Nation in a position to address greenhouse gases in the atmosphere should that science become a reality.

A lot of people don't realize that nuclear doesn't emit any CO_2, so this is something that we have out there that we can talk to various organizations who otherwise might have found some objection to it.

It is my understanding that some States, such as Connecticut, have gone—they're up to 47 percent right now, so there is a lot of potential there.

I'm eager to see the specifics of the policy when it comes out, the recommendations that are made to the President when he comes out with the national energy policy and how it fits with Murkowski's bill. I feel that there's going to be an expansion of nuclear energy in that program.

I would like for those who are testifying to include—and I'll have some questions about this—first, how can the NRC use the lessons that we've learned during their previous reform efforts to protect the public while simultaneously making the climate more favorable to putting new nuclear facilities on line?

We have made several recommendations in the four meetings that we had, beginning with July 1998, and the NRC has responded to all of these in a very positive way, and I compliment you for doing that excellent job.

Second—and when the chairman said that things move slowly around this place, well, they move slowly in the NRC, too. It is my understanding that it takes a very long period of time—some say 5 years—to implement a change in NRC regulations.

Now, we want an open policy. We want a policy that includes the public. But we have to make some changes. It's my understanding if only one of many scientists dissent, then you have to go through a whole new process that sometimes takes years, and I think we can streamline that process.

Third, there is a discuss of what Congress can do to increase the NRC's need for more resources. We are looking at, as the chairman said, new facilities permits, and how we can redistribute the existing resources before Congress starts writing massive checks for a larger workforce.

Fourth, I'd like to get a better sense of how the fees collected from the licensees are spent. It's my understanding that only about 20 percent of these fees we can really document exactly where they're going, and 80 percent are not adequately accounted for. I think, Mr. Chairman, we are going to have to do that before we make any major changes.

And, finally, I'd like to hear what other reforms must take place in the future to protect the public, as well as maintain and increase nuclear facilities as a key source of energy.

So if the NRC continues to properly implement safety-based and other common-sense reforms, our nuclear industry will continue to build on an already outstanding safety record, will thrive in a

more-efficient regulatory system, and, most importantly, provide clean, reliable, and inexpensive source of energy.

I think right now that the time is right. It wasn't right before now, but I think now we've instigated some reforms. The public is now awake and they realize that a very serious problem is out there and you can't have a national policy without having nuclear energy as a part of that.

I thank you, Mr. Chairman, for having this committee meeting. I look forward to hearing our witnesses.

I might mention—I'm sure you are aware of it, but they may not be here—we're going to have a series of stacked votes starting at 10:15, so maybe before leaving we could dispose of the first panel.

Senator VOINOVICH. That's a good suggestion. Thank you.

I think all of you are familiar with the procedure here before this committee.

On our first panel today we have Richard Meserve, the chairman of the Nuclear Regulatory Commission. Dr. Meserve will be accompanied by Commissioners Diaz, Dicus, McGaffigan, and Merrifield. For today's hearing, Chairman Meserve will provide the testimony on behalf of the NRC, and if any of the other commissioners would like to make a few brief remarks they may do so.

Chairman Meserve, we'd like you, if possible, to limit your remarks to the 5 minutes—you're familiar with the lights—so that Senator Inhofe and I have a chance to get to some of the questions that I'm sure are on everyone's mind.

We have the early bird rule here so that, as other Senators come in, they'll be able to ask questions as they come in, assuming any other Senators show up this morning.

Chairman Meserve.

STATEMENT OF RICHARD A. MESERVE, CHAIRMAN, NUCLEAR REGULATORY COMMISSION; ACCOMPANIED BY: COMMISSIONER DIAZ, COMMISSIONER DICUS, COMMISSIONER McGAFFIGAN, COMMISSIONER MERRIFIELD

Mr. MESERVE. Thank you. Chairman Voinovich, Senator Inhofe, I am pleased to appear before you today with my fellow commissioners. I would like to take this opportunity to acknowledge the strong support this subcommittee provided in the 106th Congress in enacting legislation which addresses the longstanding fairness-in-funding issue. We also appreciate the subcommittee's and full committee's efforts in support of NRC's other legislative proposals in the 106th Congress. We look forward to working constructively with you in the new Congress.

I have submitted a statement for the record, but I would like to make a brief summary.

As you know, the Commission does not have a promotional role for nuclear power; rather, the agency seeks to ensure the safe application of nuclear technology if society elects to pursue the nuclear energy option. Many of the Commission's initiatives over the past several years have sought to maintain or enhance safety while simultaneously improving the efficiency and effectiveness of our regulatory system.

We believe the Commission's most recent legislative proposals, which are described in my statement, would enhance safety and

improve our regulatory system even further. I am pleased to see that many of our proposals have been incorporated into bills now pending before Congress.

The Commission also recognizes that its decisions and actions as a regulator influence the public's perception of the NRC and ultimately the public's perception of the safety of nuclear technology. For this reason, the Commission's primary goals also include increasing public confidence.

Currently, there are 104 nuclear power plants licensed by the Commission to operate in the United States in 31 different States. As a group, they are operating at high levels of safety and reliability. These plants have produced approximately 20 percent of our Nation's electricity for the past several years. In 2000, these nuclear power plants produced a record 755,000 gigawatt hours of electricity.

The Nation's nuclear electricity generators have worked over the past 10 years to improve nuclear power plant performance, reliability, and efficiency. The improved performance since 1990 is equivalent to placing 23 new 1,000-megawatt power plants on line. The Commission has focused on ensuring that safety is not compromised as a result of these industry efforts.

The nuclear industry is undergoing a period of remarkable change. One of the more immediate results of the economic deregulation of the electric power industry has been the development of the market for nuclear power plants as capital assets. As a result, the Commission has seen a significant increase in the number of requests for approval of license transfers. These requests have increased from an historical average of about two or three per year to 20 to 25 in the past 2 years.

Another result of the new economic conditions is an increasing interest in license renewal that would allow plants to operate beyond the original 40–year term.

As the chairman indicated, the Commission has renewed licenses for five units at two sites for an additional 20 years. The thorough reviews of these applications were completed ahead of schedule. Applications for an additional five units at three sites are currently under review.

As indicated by our licensees, many more applications for renewal are anticipated in the coming years. The Commission recognizes the importance of license renewal and is committed to providing high-priority attention to this effort.

In recent years, the Commission has approved numerous license amendments that permit licensees to make relatively small power increases or uprates. Typically, these increases have been approximately 2 to 7 percent. These uprates in the aggregate resulted in adding approximately 2,000 megawatts to the grid.

The NRC is now reviewing five license amendment requests for larger power uprates. These requests are for boiling water reactors and are for uprates of 15 to 20 percent.

While the staff has not received requests for additional uprates beyond these five, some estimates indicate that as many as 22 boiling water reactors may request such upgrades. These upgrades, if allowed, could add approximately 3,000 to 4,500 megawatts.

In addition to the three already-certified advanced reactor designs, there are new nuclear power plant technologies, such as the pebble bed module reactor, which some believe can provide enhanced safety, improved efficiency, lower costs, as well as other benefits. To ensure that the Commission staff is prepared to evaluate any applications to introduce these advanced nuclear reactors, the Commission recently directed the staff to assess the capabilities that would be necessary to review an application for new construction. An examination of possible changes in our rules is underway.

In order to confirm the safety of new reactor designs and technology, the Commission believes that a strong nuclear research program should be maintained. Additionally, the Commission is reviewing its human capital to ensure that appropriate professional staff is available.

The Commission's submitted statement highlights our nuclear materials program. We have a very large number of materials-related initiatives underway. Our submitted statement also highlights other important programs such as the storage and disposal of high-level waste and spent fuel, and provides a summary of our fiscal year 2002 budget proposal.

The Commission has long been and will continue to be active in concentrating its staff's efforts to meet our statutory mandates. We are also mindful of the need to reduce unnecessary burdens, to maintain open communications with all our stakeholders, and to continue to encourage our staff to strive for increased efficiency and effectiveness.

We look forward to working with the subcommittee and welcome your comments and questions.

Thank you.

Senator VOINOVICH. Thank you, Chairman Meserve. That's an excellent statement.

Do any of the other commissioners want to comment at all on any of the subjects?

Ms. Dicus.

Ms. DICUS. Just let me say that I strongly support everything the chairman has said. I think the whole Commission does. There's nothing else I can say other than to support his statements. Thank you.

Senator VOINOVICH. Any other comments?

Mr. MERRIFIELD. Mr. Chairman.

Senator VOINOVICH. Yes.

Mr. MERRIFIELD. I'll make just a brief comment.

Senator VOINOVICH. Yes, sir.

Mr. MERRIFIELD. I do appreciate the opportunity to make a comment to you and to Senator Inhofe. It is a pleasure to come back to a committee of which I was a part of for approximately 10 years. In the 3 years that I have been involved with the Commission, I think there is a significant change from where we were, and I just want to underscore the chairman's remarks in that respect.

Three years ago we were at a point where a substantial number of plants were on the verge of shutting down or were considering shutting down. What we've seen is quite a different change, with a significant number of license renewals, license transfers, and I think the Commission has made significant progress with our new

oversight process, which, indeed, I believe, enhances safety of the reactors and our ability to oversee them in the future.

That work was the work not of a single commissioner nor of a single chairman, but the work of, I think, a dedicated and collegial Commission, three of the members of whom were there before I arrived.

One of the issues that is going to be raised today is the issue of new plant orders. This is a matter that, frankly, we had not considered very much when we were planning our fiscal year 2002 budget some 18 months ago. At that point perhaps Corbin McNeal of Exelon and maybe one or two others were considering the notion of ordering new plants.

That notwithstanding, I think the Commission has the flexibility in a disciplined and informed management process to deal with the possibility. If we are confronted with new plant orders, that's something that we're going to have to work through.

I appreciate the kind words of the chairman and other Members of the Senate in urging us to look at that issue closely and volunteering additional assistance if necessary.

Mr. Chairman, I appreciate the chance to respond.

Senator VOINOVICH. Thank you.

On another committee, Oversight of Government Management and Restructuring, where I'm subcommittee chairman, I spent 2 years looking at the human capital crisis that we have in the Federal Government, and after talking with several members of the Commission, you've got some real problems there.

There is a real desire, I think, on the part of Congress and the American people to increase the productivity of the already-existing nuclear power facilities that we have, and Chairman Meserve has made reference to the fact that you've got licenses pending before you, expect to have the relicensing, and then there's genuine, I think, interest in the private sector in building more facilities, and I'm for that.

But what concerns me is: are you going to have the human capital necessary to do the job that you're supposed to do? And we can talk all we want to about new ideas, new legislation, streamlining, and so on, but what's the Commission doing about preparing itself to be able to get the job done?

Mr. MESERVE. Senator, we very much share your concern. I know that you've been someone who has spearheaded the effort here in the Congress to evaluate this issue, and it is one that very much resonates with the Commission.

We are making an effort to do a systematic analysis of the issue. We are performing an assessment of the areas of staff competence, of the staff capabilities we need to have to do the work that we anticipate that's going to arise, and then to go through each of the gaps that exists and develop a program to identify how we're going to fill those gaps.

There has been a major effort by our human resources group for several months to get their arms around the nature of the problem in specific terms.

The challenge is going to be great, because if, in fact, there is new construction, we're going to be calling on skills that the Commission has not had to exercise for many years—for example, in

being able to do inspection of construction. That's not something that the Commission has had an opportunity to do in recent years.

We have made some suggestions as to initiatives that would help. For example, under the Federal Government's pension system, a skilled staff person who is on retirement and comes back to work at the Commission would find that every dollar comes out of his pension. They end up with no additional funds. So we have this problem with an aging staff. We've got some very highly qualified people whom we would like to bring back.

Senator VOINOVICH. Is this a problem Government-wide, or just specifically a problem that you have?

Mr. MESERVE. This is a problem. I believe it's Government-wide.

Senator VOINOVICH. OK. Any suggestions that you have that would allow you to retain or bring back individuals that you need, I'd like to have them as soon as possible, because we are gathering those together for recommendations to the Administration on things that we could do to get moving.

Mr. MCGAFFIGAN. Sir, there is a waiver authority in current law that we are currently asking OPM for permission to exercise—and I don't know whether we've heard from OPM yet—a waiver authority that would allow us to perhaps bring back 30 people. So there's a limited waiver authority in current law that we're trying to exercise. I think the chairman is suggesting that perhaps even broader authority in that area might be required.

Senator VOINOVICH. Well, it's interesting that OPM does have—and that's the other thing that we're trying to inventory, the flexibilities that OPM has right now that could be utilized. I mean, the Army Corps of Engineers used to be able to, for example, hire engineers on the spot. Somebody over there decided 4 years ago we had a bunch of engineers out there, so they stopped that. Now it takes them 6 months to hire an engineer.

It is interesting to get the flexibilities they now have, like with this waiver.

If you'd send me a note on that, I'll send them a letter and tell them, "Give them the waiver." It's what do you have now to keep people, what do you need to bring some people back. And the next issue is: what are you doing to get the word around the country? They're closing down these engineering schools in nuclear engineering. What are you doing to get them to open them up?

Ms. DICUS. Mr. Chairman, could I make a comment about that. I think my fellow commissioner would like to do that. You're right. Several nuclear engineering schools have shut down, but I was made aware—I think it's Texas A&M—I may be wrong on that, but I think was Texas A&M, in their nuclear engineering program they've almost doubled the number of students.

Senator VOINOVICH. Where is that again?

Ms. DICUS. I think it is Texas A&M.

Senator INHOFE. Phil Gramm's school.

[Laughter.]

Ms. DICUS. They've almost doubled in their freshman class last year the number of students coming in, so I think, if we deal with—and, of course, again, we cannot be promotional, and we are not, but if the nuclear industry is getting stronger, then I think

that will help. But I think whatever you can do here in Congress to support education in the area will be helpful.

Senator VOINOVICH. I'd like to ask you, if you would, first of all, confirm it's Aggies you're talking about.

Ms. DICUS. I'm not sure it is.

Senator VOINOVICH. Well, wherever it is, you read this somewhere or someone has told you this, and if this is true they have doubled I would like to know, not now, but for the record. I'm glad they're doubling, but I wonder why, what the reason was, because when a person was making a decision as to what he or she was going to do for a career, the changes that we're seeing right now had not been there, and so I'd like to know that.

Ms. DICUS. I don't know the answer.

Senator VOINOVICH. For the record.

[The information follows:]

The university identified as having recently experienced a doubling of enrollment in the nuclear engineering program was confirmed to be Texas A&M University. Dr. Alan Waltar and members of the faculty and staff of the Texas A&M nuclear engineering department have prepared a paper, for presentation at an upcoming American Society of Engineering Education meeting, that provides details regarding the Texas A&M enrollment figures as well as possible factors contributing to the recent enrollment trend. The paper is attached.

TURNING THE TIDE ON NUCLEAR ENGINEERING UNDERGRADUATE ENROLLMENT (BY ALAN E. WALTAR, MARVIN ADAMS, IAN HAMILTON, RON HART, LEE PEDDICORD, AND BETH EARL, TEXAS A&M UNIVERSITY)

The steep drop in undergraduate enrollments in nuclear engineering since the early 1990s is a serious threat to nuclear engineering in the United States and to the leadership that the United States has shown in nuclear matters around the globe. Without a feedstock of fresh nuclear engineers into the national nuclear infrastructure, America is on a clear course of self-destructicn of an extremely valuable capability.

As a consequence, substantial efforts have been expended to determine the causes for this precipitous drop (65 percent reduction in students between 1993 and 1998). Senator Pete Domenici (R-New Mexico) has sounded the alert from the U.S. Senate and Congressman Joe Knollenberg (R-Michigan) is sounding a similar alert in the U.S. House. A recent study by NEDHO (1) revealed that the gap between the number of jobs available and the qualified applicants is large and growing (projected to be about 3:1 in the next few years).

Given this backdrop, the recent rise in undergraduate nuclear engineering enrollment at Texas A&M University has been quite gratifying—our undergraduate enrollment having doubled from 1998 to 2000. Whereas this could be simply a spurious spike that cannot be sustained, we felt an obligation to share some of the efforts that have been employed to achieve this upward surge in the hopes that at least some of these techniques might be employed elsewhere. It is important that all strong nuclear engineering programs in the Nation experience similar success if we are to produce the qualified manpower that our country needs.

Listed below are the 8 steps that we at Texas A&M have employed over the past two years.

1. *Building the Case:* In order for any product to sell, the basis for sale must be solid. In the case of careers in nuclear engineering, the case today is probably as strong (if not stronger) than it was in the heydays of the 1960s and 1970s. The fundamental reason for this is that the job market is growing and the student supply is low and dropping. Students should be asked when to buy stock—with the obvious answer "Buy when the price is low!" The recent NEDHO study (1) makes it crystal clear that there currently exists a mismatch between demand and supply, and this gap is increasing rather dramatically (up to about a 3:1 ratio within the next few years). Further, nuclear power in the United States is now very stable. The plants currently online are highly valued on Wall Street and plant lifetime extension is likely to keep most of them online so that today's graduates can look forward to a full professional career at a single plant, should they choose to do so. But even beyond this, new life within the DOE (such as the Generation IV efforts) provides stu-

dents with at least some hope that new designs will receive serious attention. There are even "rumblings" of a new plant order within the United States in the relatively near future—something unthinkable even 3 years ago. And, of course, there are many careers outside of nuclear power for nuclear engineering graduates. Opportunities abound with nuclear medicine, agriculture, petroleum, general industry, law, and a whole host of fields. In fact, only about ⅓ of the nuclear engineering graduates at Texas A&M go into the traditional nuclear power field. This degree is a foundation for a rich host of opportunities in a wide variety of fields. Hence, the basic case for attracting good students into the profession is solid.

[NOTE: Step 2. was not supplied.]

3. *Rallying Industry Support:* Armed with the clear mismatch between job opportunities and the number of students in the pipeline, our next step was to contact major potential employers of our students within the State of Texas and surrounding regions. Once they saw the problem, many of the top executives agreed to participate in the formation of an External Advisory Council to see how, collectively, we might be able to reverse the downward spiral of entering freshmen. ln our case, we also asked several well-known top industry and academic leaders from around the Nation to join the Council, and we were fortunate to obtain an affirmative response from all we invited.

4. *Developing "Headliner" Scholarships:* The first step of the Council was to help our department develop a "headliner" scholarship program, entitled the Stinson Scholars Program, named after the chair of our Advisory Council, Ron Stinson (an early alumni from our program and past president of the American Nuclear Society). These are $10,000 scholarships, payable at $2500 per year over 4 years for superior students who remain in excellent academic standing within the program. We requested industrial support for these scholarships and were fortunate to obtain 4–year commitments from several corporations. We issued 9 Stinson Scholarships to start the 1999 fall semester and were able to increase the total to 14 to start the 2000 fall semester. This has been so successful (in attracting both quantity and quality of students) that our faculty sponsored 2 of these Stinson Scholarships this year from personal funds!

5. *Promoting Other Scholarships:* We, like several other programs, have been the fortunate recipient of the new DOE matching program, which has allowed us to both upgrade computer facilities and offer additional scholarships. Using the Stinson Scholarship program as our major advertising leader, we have been able to get students to apply for a variety of scholarships, including those offered by DOE, ANS, NANT, plus other department scholarships (some of which are endowed). The overall push for scholarships allowed our undergraduates to go from a total of 5 scholarships in 1998 to 33 in 1999 and 54 in 2000 (with respective yearly monetary totals going up from $5,000 to $52,500 to $100,000 in these respective years).

6. *Publicizing Starting Salaries:* The College of Engineering at Texas A&M University is one of the largest (if not the largest) in the Nation. It totals around 9500 students. The Department of Nuclear Engineering is the smallest department within the College (likely the case throughout the Nation), yet our seniors received the highest starting salaries in the entire college in 1998—plus signing bonuses in many cases! This position was maintained in 2000. Hence, we are able to tell prespective students that we have excellent scholarships and that they will be very well rewarded when they finish the program. This is a powerful message!

[NOTE: Step 7. was not supplied.]

8. *Recruiting New Students:* Armed with the above messages, our first direct recruiting step was to design and publish a new undergraduate recruiting brochure. This rather unorthodox brochure (clearly designed for the "now" generation!) contains the essence of the above messages, plus testimonials from some of our most successful graduates. Our first batch of brochures, along with a recruiting letter, went to some 200 high schools—those where some previous contact had been made. Buoyed by a highly successful "Women in Discovery" Program (2), which featured the legacy of Marie Curie, the list of schools currently being contacted has been extended to approximately 650. For those high school students accepted into our program, faculty and students within our current program placed telephone calls. This was done in recognition that many of the best students are accepted into several programs, and we wanted to maximize the "catch" rate. In addition, a special letter was sent to these students by a CEO at a nearby nuclear utility—congratulating them on their choice of major and offering a summer job to all students in good standing at the conclusion of their freshman year! Some actual recruiting visits were made to high schools, but that has been minimal to date. We hope to substantially increase this in the near future. Teacher workshops continue to be very help-

ful, because once teachers are aware of the incredible opportunities in nuclear engineering, they are far more likely to pass that enthusiasm on to their students. Having conducted one successful workshop last year, we have already completed another one this year and hope to do several more. Our faculty members have also given several talks and workshops on campus for high school students visiting for other campus-wide events.

9. *Recruiting On-Campus Students:* Freshmen admitted to the College of Engineering at Texas A&M are required to declare a major upon arrival. However, the curricula for freshmen are essentially the same for all majors. The College has two "Open House" nights each year (one each in the fall and spring semesters), in which students are required to attend two departmental presentations. They generally attend the presentation given by the department of their declared major, but they must attend one other session. We push hard for them to select the nuclear engineering presentation as their other choice, and we provide information condensed from the above material (items 1 through 5) by faculty and students. Our most persuasive speakers are our top students, who carry unbridled enthusiasm for our program.

10. *Emphasizing Retention:* Perhaps our best recruiting tool is the way we try to treat students once they are accepted into the program. For example, this year our student leaders went the "extra mile" by personally greeting all new students as they came for campus orientation. In addition to making them feel welcome, they invited them to a "get acquainted" party sponsored by the Department shortly after the opening of classes. We were especially fortunate this year to have ANS President Jim Lake in town in early September, so we built the party around him. Approximately 100 students came to the barbecue. This occasion provided a particularly good opportunity for recognizing the scholarship winners. We also inaugurated a mentoring program, whereby new students mix with upperclassmen and graduate students (a range from freshmen to Ph.D. students)—along with one or two faculty members—for free pizza approximately every two to three weeks. There is no set agenda, but the personal interactions and networking that naturally transpire seem to be very meaningful to students at all stages of their careers. Also, we strongly support student professional groups. Students participating in student activities are rewarded by department sponsorship of travel to national and international professional society meetings. For example, 26 students within the department were sent to France in the fall of 1999 to a conference in Paris sponsored by the French Nuclear Student Section. An average of about two dozen students are sent to national ANS and HPS meetings each year. Also, 6 students were sent to Russia as part of a NATO conference this past summer. Other students have been able to attend meetings in Japan and Belgium. This type of support is highly appreciated by the students, and they readily share such experiences with students in other departments. We believe this type of attention and support is responsible for both a highly motivated student population and a major reason we attract several students each year who decide to transfer in from other departments.

Whereas it is difficult to ascertain which of the above approaches is most influential in our recruiting process, we tend to believe that the hot job market (high paying jobs) and large scholarships are the primary ingredients for the rapid increase in undergraduate enrollment. As shown in figure 1, our undergraduate enrollment plummeted to a low of 55 in 1998 (mirroring the national trends), but has subsequently climbed to 109 in the fall of 2000 (a doubling in 2 years). We fully recognize that this trend may not be sustainable. It is still a very difficult job to attract good students into a profession that has received such bad press within the past decade. But we are gratified by the rebound recently experienced and hope that at least some of the efforts we have employed might be equally successful elsewhere.

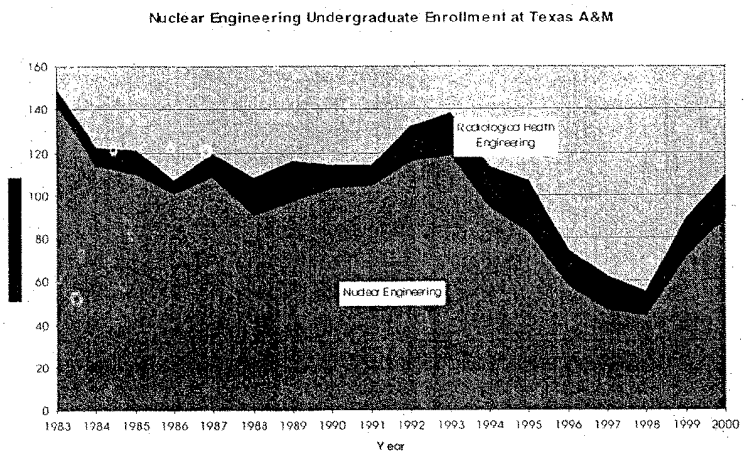


Figure 1. Nuclear Engineering Undergraduate Enrollment at Texas A&M University

Mr. DIAZ. If I may, just add a comment. Since I came from a nuclear engineering school and I just visited there, I think there is now a different environment. I went to the University of Florida and met with the students 3 weeks ago, and, you know, there was a different feeling. I think they think that there is now the potential for them to contribute to our society, and before it was almost like a black cloud that, you know, was almost like a stigma. And I think the students feel that there is a new opportunity and that this will bring renewed interest in the career.

But one point, Senator, that I know very well is that the nuclear engineering students are now the highest-paid of all outcoming bachelors in the United States. The entry salary for nuclear engineers is $57,000 because there are so few of them. And so they are—the ones that are in there are actually receiving significant benefits.

And I might offer a personal comment to Senator Voinovich. Senator, I'd be willing to make my own personal contribution to the issue of human resources and postpone my retirement.

[Laughter.]

Senator INHOFE. Mr. Chairman.

Senator VOINOVICH. Go ahead.

Mr. MCGAFFIGAN. Sir, just on the university issue, I'd just add one more data point.

Cornell, MIT, and Michigan are thinking about shutting down their research reactors. Mr. Magwood from the Department of Energy testified, I believe, to the Senate Appropriations Committee last week to that effect and was looking for emergency funds in order to—and I think Senator Domenici is going to be supportive—to keep those research reactors alive.

I think there is a delay. I think Senator Inhofe is right. If I were counseling a young person, I would counsel them to go into nuclear engineering today. They'll be at the leading edge of, I think, a rebirth of this industry. But that's not what the academic deans at some of these universities think. They see unused research reac-

tors, they see small nuclear engineering departments, and, unfortunately, there has been a trend in recent years to shut them down. It is primarily the Department of Energy's job. They're the agency that funds research in universities, and they are on top of it and, I think, trying to do something about it.

Mr. MERRIFIELD. If I may just layer on top of that—not to take your time—two things. First, I agree with Commissioner McGaffigan. The value of the research reactors is paramount. For our agency, the largest recipient of our research funding from the university standpoint is the University of Michigan. If that reactor were to close, there are a number of programs that we have in the research sector which would be endangered. We would have to find some place else to take those. So for us that reactor is quite important.

Second thing, I agree with him in terms of the lag time with the management structure within the engineering schools. I had an opportunity to visit the University of Maryland to do some recruiting this year. I found students who were very excited. I found professors who were very excited about what was going on. And I found an engineering school dean who was very doubtful of the future of nuclear power and who was very much considering the notion of whether they ought to keep their reactor and their undergraduate program. So there is a disconnect and there is a time lag which is of concern.

Senator VOINOVICH. I'll tell you what I—I'd just like to finish up—what I'd like to do would be for somebody in your shop to identify the schools that are active, the reactors that are out there, and maybe Senator Inhofe and maybe some of the other members of the committee might be willing to send letters out to the schools indicating to them that it appears that we know we need more people in that area.

I was with Governor Engler the other day and the former president of the University of Michigan, a nuclear engineer named Dudersdoff. We talked to them about revisiting that issue, and even with the reactors to just have a little plan in place where we can highlight the need and just kind of give them a heads-up, and then if there is some additional Federal money that we need to have to keep things on the road, that we ought to do that. But we need a strategic plan put together to deal with the human capital crisis, and, frankly, I'd like to have your best thoughts about how, in your opinion, you can deal with the current problem, bring more people back, and what other tools do you need to attract people into your agency.

Mr. MESERVE. We'd be happy to submit something, Senator. We would very much welcome that.

Senator VOINOVICH. OK.

[The information referred to follows:]

The following is a list of schools which have research reactors with an active operating license. The University of Illinois has an operating license but has ceased operations. The first three schools listed have publicly announced their intention to shut down their research reactors in the near future. Please note that the NRC has not received formal correspondence concerning a shutdown of any of the listed facilities: Cornell University TRIGA; Massachusetts Institute of Technology; University of Michigan; Idaho State University; Kansas State University; North Carolina State University; Ohio State University; Or-

egon State University; Pennsylvania State University; Purdue University; Reed College; Rensselaer Polytechnic Institute; Rhode Island Atomic Energy Commission; Texas A&M University; University of Arizona; University of California at Irvine; University of Florida; University of Maryland; University of Massachusetts—Lowell; University of Missouri—Columbia; University of Missouri—Rolla; University of New Mexico; University of Texas; University of Utah; University of Wisconsin; Washington State University; Worcester Polytechnic Institute; University of California—Davis, McClellan.

Senator VOINOVICH. Senator Reid has come in, ranking member of the main committee. Senator Reid, would you like to make some comments before Senator Inhofe asks his questions?

Senator REID. Senator Voinovich, I apologize to everyone for being late. I went to our old office place and then somebody sent me to the Russell Building, and I've been running around for about 25 minutes trying to find this, so it's not anyone's fault except my staff, and I apologize for that.

Being late, I feel very discourteous reading a statement. I have some very serious questions. I will ask permission of the Chair to submit my statement as if read.

[The prepared statement of Senator Reid follows:]

STATEMENT OF HON. HARRY REID, U.S. SENATOR FROM THE STATE OF NEVADA

Mr. Chairman, I want to thank you for calling this hearing today to allow us to discuss oversight over the nuclear power industry.

Today we are going to hear from industry and advocacy groups about the issues with the NRC and about plans for new nuclear power plants.

I can't imagine having this discussion without raising the specter of dealing with the pollution produced by the industry. This is pollution that we must monitor not for 10, not for 100, but for more than 100,000 years.

As you all know, the State of Nevada has been chosen as the only site studied in the Nation for a proposed underground nuclear waste storage facility.

But perhaps you didn't know that Yucca Mountain is only 90 miles from Las Vegas, Nevada's largest and one of America's fastest growing cities. In addition to being home to more than 1.3 million Nevadans, Las Vegas and its neighboring communities draw more than 30 million visitors each year.

The Department of Energy is in the process of scientific studies into Yucca Mountain. I am aware that there is tremendous pressure being applied by the nuclear industry to make the science fit the site.

But, Yucca Mountain just is not the right answer.

What does all this have to do with today's hearing? The answer is simple: before we consider rushing forward to build new nuclear power plants we need to address the nuclear waste question in a meaningful way.

Not doing so would be like Henry Ford designing and building every part of the Model T except the exhaust. No one would consider mass producing such a defective car.

We can choose to invest in the truly sustainable generating sources such as wind, solar, geothermal, efficiency and conservation:

Well-sited wind farms generate energy at rates of less than 5 cents per kilowatt-hour and will soon get to 3 cents per kilowatt-hour. That's competitive with the cheapest fossil fuels and nuclear power—without the harmful pollution.

A 10,000 square mile region of Nevada could supply our Nation's entire electricity needs with existing solar technology. With the right investments this technology will only improve.

Energy efficiency continues to save energy at less than a few cents per kilowatt-hour.

We can choose to end the tremendous Government subsidies of the nuclear power industry:

Nuclear power generation is a mature industry that has outgrown the billion-dollar-a-year Price-Anderson subsidy. We should allow the market to decide if spending $2000–$3000 for every kilowatt of nuclear power is the right kind of investment to make.

I don't think the market will be willing to take that kind of financial risk.

Finally, I would like to raise some specific issues with the Nuclear Regulatory Commission.

First, I am concerned by the pressure the Nuclear Regulatory Commission continues to place on the Environmental Protection Agency (EPA) over the Yucca Mountain radiation standard.

According to the 1992 Energy Policy Act, the EPA has the legal responsibility to set this standard.

In October of last year, Vice President Cheney visited Reno, NV and assured the residents of my home State that the EPA would be the lead agency on this standard. They also indicated that they would support a rigorous standard from the EPA which would fully protect families in Nevada.

The residents of Nevada deserve to have vital groundwater resources that are as safe as anywhere else in the country.

Second, I have concerns about the recent efforts to eliminate restrictions on foreign ownership of nuclear plants. We don't allow foreign control of airplane manufacturers, why should we allow foreign control of our nuclear power industry?

Today, nuclear power plants are bought and sold like used cars.

We already have several 50–50 partnerships between United States and foreign firms, and Westinghouse—a major supplier of maintenance, parts and services for the industry—is now a wholly-owned subsidiary of British Nuclear Fuels, Ltd.

This Administration talks about the need to decrease foreign control of our domestic energy market. We should start by ensuring domestic ownership of the nuclear power industry.

Third, I am concerned with the erosion of public participation in the licensing of new plants and the relicensing of existing ones.

The NRC has chosen to keep the formal hearing process for the licensing proceedings related to Yucca Mountain. But where is this same protection for licensing and relicensing?

If the industry truly has a safe, efficient, and reliable product they should not be concerned with holding formal hearings to discuss the extension of the licenses.

It is time to bring some rational thought to the debate over nuclear power.

No longer should we discuss the virtues of nuclear power without addressing the vices of nuclear pollution.

No longer should we use Government subsidy to prevent the extinction of this dinosaur of an industry.

We have an obligation to our children to ensure that our short-term energy needs are not met with long-term environmental neglect.

I look forward to hearing from our witnesses today on these important issues.

Senator REID. I do have some questions that I would ask be returned to me and the committee within 2 weeks. As everyone knows, it is a very serious issue for me. Some say the difference between nuclear waste in Nevada and not is a fair treatment by the NRC, so I would ask respectfully that my questions be answered at the earliest possible time.

Senator VOINOVICH. Thank you.

Senator Inhofe.

Senator INHOFE. Well, yes, let me get into something else, and that is I perceive a problem, and that is in our radiation policy it is somewhat duplicative, at least with the EPA. It has been my opinion that the EPA's regulation portion of this is based more on policy than on science.

I'd like to hear from any of the commissioners how you feel this can be corrected. Do we have a duplication of regulation that is unnecessary at this time?

Mr. MESERVE. Well, I know that Senator Reid is going to ask some questions dealing particularly with Yucca Mountain. Let me answer the question in terms of a more general issue—namely, the decommissioning of nuclear sites.

There is a duplication of effort that arises from the fact that, for our licensees, we have an obligation under the Atomic Energy Act

to supervise those licenses and make sure that the facilities are decommissioned properly.

EPA has overlapping jurisdiction with us as a result of CERCLA, the Superfund Act, and that has resulted in at least some disagreements that have arisen from time to time in that our standards for decommissioning are defined by rule, and they specify certain limits that we anticipate our licensees are to meet.

EPA has not proceeded by rule, but does have a policy where, for the cleanup of Superfund sites, it would require cleanup to a different limit. That has created confusion with our licensees. They fear that they might clean up to satisfy our standard and then be left with an obligation under Superfund, after they have satisfied our requirements, where the EPA might come in and demand additional requirements of them.

We believe that the EPA standards are unnecessary and do not have an adequate scientific foundation.

Senator INHOFE. I see. Any other comments on that?

Mr. MCGAFFIGAN. Mr. Chairman, I just might add on this point about rulemaking, we went through a very, very complex rulemaking to establish our decommissioning standard back in 1997. It was unanimously supported by the Commission. We did look at what EPA was proposing. That was something, indeed, that we had put in our proposed rule to get comments on, and when we did calculations to look at what it would take to get to the EPA standard, we found either negative health benefits or cost per life saved that ran into the tens of billions of dollars, and we could not justify going to the EPA limit. For instance, their strontium–90 maximum contaminant level is 6/100ths of a millirem per year. That's 3 hours in the Senate waiting room if you want to translate it into your own life. That's just a very, very problematic standard.

[Laughter.]

We actually did cost/benefit analysis, and we just could not justify EPA's proposed standard. There are voluminous documents we would be happy to share with your staff that documented why we ended up where we did in our rule.

Senator INHOFE. But, Commissioner, what I have heard on this is that they are regulating to 1/10th or 1/15th of what is considered now to be safe. Is that information fairly accurate?

Mr. MCGAFFIGAN. Sir, they sometimes regulate——

Ms. DICUS. Less than that.

Mr. MCGAFFIGAN. With the strontium–90 at the 6/100ths of a millirem per year level, they are regulating to 1/10,000th of background radiation.

Senator INHOFE. And the cost of regulation when you get to those levels is far greater than initial costs?

Mr. MCGAFFIGAN. It makes no sense to regulate at those levels, in my opinion, sir.

Senator INHOFE. One other question. The recommendation you made under Price-Andersen renewal, it was made at a time, it's my understanding, that you felt there would be about 50 percent of the number of plants that there now appears that there will be out there, and so I assume, when you're talking about increasing from $10 million to $20 million is because you'd only have half as many plants paying that premium, and now that all of them—it appears

to be twice that many. What is your current opinion and recommendation?

Mr. MESERVE. You're quite correct. There was a report we submitted in 1998 that proposed the retrospective premium be changed from $10 million per reactor to $20 million per reactor per year, and that was based, exactly as you said, on the assumption that was then the current view that there would be a decline in the number of nuclear plants. That is unlikely to be occurring because of license renewal. So the Commission has revisited that recommendation, and we now no longer recommend that an adjustment in the retrospective premium be made. And we will be happy to submit a letter for the record to that effect.

Senator INHOFE. Yes. I would like to see it. I had not seen anything as far as a change of your recommendations, so we'd like to have that.

Mr. MESERVE. We have recently been conferring on that issue.

Senator INHOFE. Regarding Price-Anderson, provide NRC's change of position on the maximum annual retrospective premiums based on the new situation for license renewals ($10 million vs. $20 million as in 1998 report) in a letter to the subcommittee and to me. Please provide information this week or early next week.

[The letter provided to the subcommittee and Senator Inhofe follows:]

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

May 11, 2001

The Honorable George V. Voinovich, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

In 1998, pursuant to Section 170p. of the Atomic Energy Act, the Nuclear Regulatory Commission (NRC or Commission) submitted to the Congress NUREG/CR-6617, "The Price-Anderson Act -- Crossing the Bridge to the Next Century: A Report to Congress."

In that report the NRC recommended renewal of the Price-Anderson Act because that Act provides a valuable public benefit by establishing a system for the prompt and equitable settlement of public liability claims resulting from a nuclear accident. That remains today the strongly held position of the Commission.

The Report also included, among others, a recommendation that the Congress consider amending Section 170b(1) to increase the maximum annual retrospective premium installment that could be assessed each holder of a commercial power reactor license in the unlikely event of a nuclear accident. The NRC suggested that consideration be given to doubling this ceiling from the current sum of $10 million to $20 million per year per accident. The total allowable retrospective premium per reactor per accident would remain unchanged at $63.9 million in 1988 year dollars (now $83.9 million as adjusted for inflation). The maximum retrospective premium assessments constitute the mandated secondary layer of insurance, above and beyond the primary liability insurance that licensees must maintain.

The Commission recommended consideration of an increase to $20 million because it then appeared likely that in the coming decade a number of reactors would permanently shut down. The effect of these shutdowns would be to reduce the number of contributors to the reactor retrospective pool. Fewer contributors would in turn reduce the funds that, in the event of a nuclear accident, would become available each year to compensate members of the public for personal or property damage caused by the accident. Increasing the maximum annual contribution available from each reactor licensee would increase the amount of "up front" money to assist the public with prompt compensation.

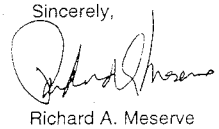
Acting on the Commission's renewal recommendations, this session several sponsors introduced bills in the Senate which would renew the Price-Anderson Act. Each of these bills would raise the retrospective premium to $20 million per year per licensee.

Recent events have led the Commission to reevaluate its 1998 recommendations. There is now a heightened interest in extending the operating life of most, if not all, of the currently operating power reactors, and some power generating companies are now examining

whether they wish to submit applications for new reactors or complete construction of reactors that have been mothballed. In view of these developments, the Commission does not believe that there is now justification for raising the maximum annual retrospective premium above the current $10 million level. Accordingly, the Commission withdraws its recommendation that the Congress should consider raising the maximum annual retrospective premium to $20 million and recommends, instead, that the premium remain at the current $10 million level.

The Commission appreciates your early interest in renewing the Price-Anderson Act and hopes that these views will assist you in your consideration of Price-Anderson Act renewal legislation.

Sincerely,



Richard A. Meserve

cc: Senator Joseph I. Lieberman
Senator James M. Inhofe

Senator INHOFE. Let me clarify it for Commissioner Dicus. When I said "for the record," I meant in writing when you find out, not for the record today.

Thank you, Mr. Chairman.

Senator VOINOVICH. Senator Reid.

Senator REID. Mr. Chairman, thank you.

During the presidential campaign, Dr. Meserve, President Bush and Vice President Cheney clearly stated in Nevada that the EPA should be the lead agency in developing the standard. Do you agree with the President that EPA should be the lead agency?

Mr. MESERVE. I think this is, in fact, an issue for the Congress to decide and not for any particular agency. The statute provides that EPA is to have authority to set the standards, and when and if EPA does that, then we will conform our requirements to them.

We have had a dispute with EPA as to the standards, as you are aware, and I have suggested, the Commission has suggested that one way to resolve that would be to put the NRC in charge, not to have two different agencies that have overlapping responsibility. But we are going to comply with the law.

Senator REID. Well, that's kind of like what just took place in the Senate. If you don't like the rules, you fire the umpire. We just had our parliamentarian fired. That's kind of what I see you are doing here. You don't like the rules, so you want to change them, and you've already indicated that EPA should the lead agency, right?

Mr. MESERVE. I indicated the statute provides that EPA is to have the authority to set the standards. There is no rule, in fact, that is in place at the moment. As you know, the EPA has a final rule that is in a concurrence process now.

Senator REID. That's the issue. The EPA would have issued the standard a long time ago but for the pressure of your entity and others from the nuclear power industry trying to force them not to have the rule that they feel is the right one. You're aware of that, aren't you?

Mr. MESERVE. Well, I am aware that we have had disagreements with EPA on a matter of principle. We're not engaging with EPA on behalf of the nuclear industry. We believe that those standards should have an appropriate form. We are supported in that by the National Academy of Sciences. We are supported by the way international organizations regulate these materials. So we are trying to push for an appropriate rule as we see it.

Senator REID. How much money has the NRC spent since 1992 to develop independent radiation release standards for the Yucca Mountain Nuclear Waste Repository? Do you know?

Mr. MESERVE. I don't know, Senator. I'd be happy to find that information and submit it for the record.

Senator REID. OK. Do you know how much staff resources have been dedicated to that task?

Mr. MESERVE. I don't know, but, again, there has been a substantial amount of staff effort that has been underway for several years because of the role that Congress defined for NRC with regard to Yucca Mountain. I will have to submit for the record the details.

Senator REID. We would appreciate your doing that. How much money and staff resources has the NRC spent since 1992 to develop

its independent high-level waste repository ratiation standard for Yucca Mountain?

[The information requested follows:]

It is our understanding (based on the testimony transcript and discussion with you staff) that the question relates only to the development of "independent radiation release standards" or dose limits. The staff estimates that approximately 2 to 4 staff weeks and $10,000 in contractor expenses were incurred in specifying the proposed radiation standard and responding to public comments regarding the radiation standard. This expenditure is small because it reflects only those costs associated with NRC's specification of an annual, individual, all-pathway dose limit of 0.25 MSv (25 mrem) and not the costs associated with development of other aspects of the NRC's regulations.

The Energy Policy Act of 1992 specified the development of a Yucca Mountain-specific repository standard that would be based upon and consistent with the findings of the National Academy of Sciences (NAS). The NAS released their report on the technical basis for a Yucca Mountain standard in August 1995.

The NRC specified a dose limit in its proposed regulation for Yucca Mountain that is generally consistent with the NAS report, recommendations of the International Commission on Radiation Protection, and NRC's dose limits for decommissioning of nuclear facilities and low-level waste disposal [i.e., annual, individual, all-pathway dose limit of 0.25 mSv (25 mrem)]. Because the dose limit was already in use in NRC regulations, limited effort was necessary for its specification in proposed 10 CFR Part 63.

Under its authority, NRC is responsible not only for implementing the EPA standard, but also for specifying other criteria for ensuring safety of the Yucca Mountain repository (e.g., performance assessment, performance confirmation, emergency planning, and quality assurance). The total NRC resources that have been spent since release of the NAS report to develop the NRC regulations are approximately $800,000 (including NRC staff and NRC contractor costs associated with the Center for Nuclear Waste Regulatory Analyses.) The staff resources reported are for work directly related to developing the regulation.

Senator REID. Also, Doctor, isn't NRC's responsibility to license a site once DOE submits an application?

Mr. MESERVE. Yes, we do that. We do other things, as well. We set standards, we would have an obligation to supervise the construction of the site and the operation of the site and the closure of the site. It goes beyond just simply the licensing.

Senator REID. That would be 10,000 years from now closing the site?

Mr. MESERVE. Pardon me?

Senator REID. That's 10,000 years from now in closing the site?

Mr. MESERVE. Well, the closure is the closure after the waste has been in place, and then after some period of monitoring. I believe it has been NRC's—excuse me, DOE's intention to do what they call "close a site," which is to seal it, and there would be no further necessary DOE involvement at the site in terms of penetration into the area where the waste is stored.

Senator REID. Have they told you how long it would take to fill that?

Mr. MESERVE. Pardon me? How long it would take to fill it? No, I don't know that.

Mr. MCGAFFIGAN. Sir, I think the——

Senator REID. Why does the Commission believe it has any role in setting environmental standards for the site?

Mr. MESERVE. Well, as part of the licensing process, we are subject to NEPA process, and so we do have an environmental role that is imposed on us by NEPA. The statute provides that we are to rely on a DOE environmental impact statement to the extent we can.

Senator REID. Somebody—did I hear somebody trying to say something?

Mr. MCGAFFIGAN. Sir, I've lost the train of thought. We have a role to write implementing regulations.

Senator REID. Better than never having had a train of thought. [Laughter.]

Mr. MCGAFFIGAN. We have a role in implementing regulations to the EPA standard.

Senator REID. Say that again now.

Mr. MCGAFFIGAN. We write our rules that go into more detail than the EPA umbrella standard, and that process has been underway for some time. As you know, early in that process, because EPA had not yet established an overall standard, we proposed a standard back a couple of years ago. But, as the chairman has said, consistent with the statute, once EPA did issue its proposed rule our intention now is to wait for their final rule and conform to it.

But there is a regulatory role that we have, in addition to the licensing role, that is established by statute.

Senator REID. So you don't think the President or Vice President said anything that was improper saying that EPA should be the lead agency in developing the standard?

Mr. MCGAFFIGAN. That's law, sir.

Senator REID. So I guess my last question is: then why is it appropriate that you are trying to get them to change the standard before it is issued?

Mr. MCGAFFIGAN. Sir, we are a commenting entity, as the National Academy of Sciences and other people are, and it is appropriate for us to make comments about the EPA rule as we did publicly, and our comments on the EPA rule are a matter of public record, just as EPA comments on our rule are a matter of public record.

Mr. MESERVE. Just as you, Senator, have a right to submit comments to EPA, we do, as well.

Ms. DICUS. And, if I could support the comments that we have made by this Agency to the EPA, it is our right to do that, and we have done that.

Now, we understand they have a statutory authority to set the standards, but we can also make comments on that standard.

Senator VOINOVICH. We have a vote scheduled, and I haven't any further questions except one general one, and, Dr. Meserve, you've kind of handled it, but it gets back to a conversation we had some time ago, and that is I really am interested in your best thoughts—and share this with your fellow commissioners—the issue of if we wanted to jump-start the productivity of already-existing facilities and create an environment where it would be easier for new facilities to be built, from your perspective what things would be necessary in order to get that done?

And, again, the issue of the human capital issue is also one that I'd like to hear from you, not so much for this committee but for the other committee that I chair in terms of the crisis that we're facing. I'd love to use your agency as an example of how this human capital crisis is impacting upon our Federal Government. That would be very helpful to me.

Mr. MESERVE. We would very much welcome the opportunity to assist you.

Senator VOINOVICH. We would like recommendations to help the human capital problems. What is working at the NRC? What do you have in place to keep people (staff)? What are we doing to bring people back and to attract new hires?

[The information referred to follows:]

The staff is developing a comprehensive plan for implementing a systematic strategic workforce planning process at NRC to address core competency issues. This plan will address workforce planning issues, such as an aging workforce, potential lack of critical skills, succession planning, and the effect of external labor market trends on the availability of needed skills.

NRC has put in place a number of promising strategies to retain the attract employees. These strategies include:

- Hire employees prior to the departure of experienced, technical staff to facilitate knowledge transfer
- Increase compensation/number of higher level positions
- Increase permanent entry level interns and cooperative education students
- Provide grants for college students
- Implement student loan repayment programs
- Implement fellowship programs for employees to develop skills unique to NRC
- Grant Waivers of Dual Compensation Limitations where appropriate
- Continue to use recruitment bonuses
- Continue training and retraining efforts

The agency will continue to use these strategies to retain critical technical skills. We will continue to provide robust training opportunities, flexible work schedules, high quality working conditions, a family-friendly work environment, and employee services (e.g., up-to-date information technology tools, onsite daycare, health and fitness programs.) The NRC has expanded its outreach activities, established competitive entry-level salaries, and will use recruitment bonuses, and establish fellowship programs. Through the use of these strategies, NRC seeks to address the human capital challenge effectively.

Senator VOINOVICH. Thank you. I thank the panel very much and we'll be back——

Senator INHOFE. Let me ask one thing for the record here.

Senator VOINOVICH. Sure.

Senator INHOFE. In my opening statement I commented that I had heard that 80 percent of the fees that had been collected from licensees don't have adequate accounting. I'd like to kind of get some kind of a feel from you in writing for the record on that, and what can be done to change that. Please respond to the adequacy of accounting for the money we collect from fees—as well as money from the waste fund, general fund, and so forth. Also, explain what percentage is from Part 170, Part 171, waste fund, and general fund.

[The information referred to follows:]

Approximately 7 percent of the NRC's fiscal year 2001 budget is appropriated from the Nuclear Waste Fund and the General Fund. The remaining 93 percent of the budget is offset through fees charged to NRC licensees.

The assessment of Part 170 and Part 171 fees is non-discretionary and in compliance with statute and case law. The agency collects approximately 25 percent of its required fee amounts from Part 10 fees for specific services. These fees recover the NRC's costs of providing specific benefits to identifiable applicants and licensees. Examples of the services provided include review of applications for new licenses, the review of applications for renewal of existing licenses, the review of requests for license amendments and inspections. The remainder of the fees are collected through Part 171 fees (annual fees) to recover generic and other regulatory costs not otherwise recovered through Part 170 fees. These annual fees recover the agency's budget associated with activities such as: allegations; contested hearings; research; development of risk-informed regulations; rule development; maintaining the incident response center; international programs; oversight of Agreement States;

and issuance of orders. NRC's basis for calculating fees are discussed in our annual proposed fee rule and are subject to public review and comment.

The agency complies with the appropriate laws, regulations and generally accepted accounting principles for its accounting operations, including receivables such as fee collections. The NRC's financial records are audited annually by the NRC Inspector General. The NRC has received an unqualified financial statement audit opinion each year since fiscal year 1994.

Mr. MCGAFFIGAN. Sir, could I just comment on that? About 80 or 79 percent comes from annual fees, and the other 21 percent comes from fees that we attribute to a particular licensing action or particular inspection. That doesn't mean the 80 percent aren't accounted for. It means that they are used for things like research, paying the rent on the building, and the Commission developing rules. There's no issue of waste in that 80 percent. It's largely an accounting device.

We have—for reasons of policy, over time made decisions, for instance, to have lower fees for small businesses, to not charge fees to universities, to not charge first-of-a-kind fees, for instance, or to pro-rate when somebody is the first license renewal—such as Calvert Cliffs. We didn't charge them the full fees because we were learning how to do license renewal, so we had a discount for them.

There's a lot of that that goes on. The pebble bed reactor—if there's going to be research related to that reactor, that research would be charged to all reactor licensees, not to Exelon because it's a first. We believe the benefits accrue to the whole industry.

So the 20 percent versus 80 percent is largely an accounting artifice rather than an issue of indicating that there's any waste. We don't believe there is.

Senator INHOFE. Perhaps that's true then.

Ms. DICUS. Absolutely.

Senator INHOFE. And perhaps I didn't get the right information concerning that. So if the other 80 percent is properly accounted for, then just let us know this.

Mr. MCGAFFIGAN. Sure. Yes, sir.

Senator REID. Chairman Voinovich, if I could just say one last thing—because my time was up—my concern, Dr. Meserve and other members of the Commission, is that you're doing more than submitting comments. I don't think that you should be involved in inter-agency review process and other things that are simply more than my commenting on a rule, and I think you're going way beyond commenting on a rule, and I don't think it is appropriate.

Senator VOINOVICH. Thank you, Senator.

I have one—and I'm going to ask you to submit it. I just received a letter from a constituent, very important, Dr. Silverstein, who is at the Department of Nuclear Medicine at University Hospital in Cincinnati. He basically states that, "The amendments to the 10 CFR part 35 are before OMB for review. In my opinion, the proposed NRC regs add to the cost of health care without improving patient safety." And he goes on to talk about some of the other things that he's concerned about.

He also mentions that he feels that the Commission ignored the advice of the National Academy of Science Institute of Medicine. It's a pretty specific question, and I'll have it submitted to you and I'd like to have a written explanation and response to Dr. Silverstein's letter to me.

Mr. MESERVE. We'd be glad to do that, Senator.

Senator REID. Senator Voinovich, would you indicate to the members of the panel here today what we're going to do? We should have a vote. I don't know if it's——

Senator VOINOVICH. Yes. We're going to go vote, and we've got another one or two and we'll come back and convene the hearing and hear from our other witnesses.

Senator INHOFE. I understand, Mr. Chairman, that we have three votes, and if we can get a tail wind with this one we could get back probably by close to 11:00.

Senator REID. You're kidding? Not a chance.

Senator INHOFE. That gives them 10 minutes more than it says it's going to take. Let's just say—you're in the leadership.

Senator REID. That's why I laughed.

Senator VOINOVICH. Well, we will try.

Senator INHOFE. One last thing. I was talking to my staff about this 80 percent, and I still would like to get this down to show the accounting where it is.

Mr. MESERVE. Sir, we'd be glad to do it.

Ms. DICUS. We'll do that.

Senator REID. Thank you, Mr. Chairman.

Senator VOINOVICH. OK. What we're going to do is that—yes, we'll be in recess for 30 minutes and come back. Again, I apologize to the witnesses that are here, other witnesses that we have to testify today, but if you know anything about the Senate, we just do the best we can.

Senator REID. This panel may be excused then?

Senator VOINOVICH. Yes, it is. Yes. Thank you very much. You will be getting some other written questions from members of this committee, and we're going to leave the record open for 2 weeks. Thank you.

Mr. MESERVE. Thank you.

Senator VOINOVICH. Thank you very much.

[Recess.]

Senator VOINOVICH. The committee hearing will come back in session. I apologize to those testifying today. Senator Reid reminded me he said it would be 11:00 and he was right. We are hopefully going to get some rules to say if it is a 10–minute vote it's a 10–minute vote, and if you're not there you miss voting. Again, I appreciate your all being here.

Our next panel will be: Mr. Joe Colvin, president and CEO of the Nuclear Energy Institute. Following Mr. Colvin will be Mr. David Lochbaum, nuclear safety engineer at the Union of Concerned Scientists; Mr. Oliver Kingsley, president and chief nuclear officer of the Exelon Energy Corporation; Ms. Gary Jones, associate director for energy, resources, and science issues at the General Accounting Office; and Mr. Steven Fetter, managing director of Global Power Group, Fitch IBCA.

We will begin testimony with Mr. Colvin.

Mr. Colvin.

STATEMENT OF JOE F. COLVIN, PRESIDENT AND CEO, NUCLEAR ENERGY INSTITUTE

Mr. COLVIN. Thank you, Chairman.

Chairman Voinovich, I really appreciate your holding this hearing. I have submitted my testimony for the record in written form, and I would like to summarize that for today.

Today I'd really like to focus on three key points. First is nuclear energy's important role in a comprehensive national energy policy for our Nation; second, the clean air benefits of nuclear energy; and, third, regulatory oversight of the industry.

First, national energy policy. Nuclear energy in the United States is really a tremendous success story and has played a major role as one of the engines driving our country's economic growth. Our 103 nuclear power plants that are operating provide over 20 percent of our Nation's electricity. They provide that electricity safely, reliably, competitively, and, importantly, without the release of pollutants to the environment.

In fact, the increase in nuclear power production over the last decade has accounted for nearly one-third of the growth in electricity demand during that time period, and nuclear industry production has provided a hedge against disruption of our electricity supply.

Nuclear power plants are really a mainstay of our electricity grid. They can operate at full capacity for up to 18 months without refueling, and they are far less susceptible to disruptions by weather and other electricity sources.

The second point I wanted to mention briefly are the clean air benefits of nuclear energy. Nuclear energy plays a vital role in protecting our air quality and is the largest source of emission-free U.S. electricity. Nuclear power plants are also vital to meeting our Clean Air Act emission standards for both sulfur dioxide and nitrous oxide, and if nuclear were removed from the energy mix many States and regions simply could not comply with the requirements of the Clean Air Act.

Our electric generating facilities in our Nation, as we move forward to supply the energy needs, face significant emission reduction requirements. The nuclear power plants really, by preventing air pollution, play a major role in pollution compliance. In fact, the United States simply cannot meet the broad spectrum of Clean Air Act requirements without continuing and expanding nuclear technologies.

My last point, Mr. Chairman, is regulatory oversight. In April of 2000 the Nuclear Regulatory Commission implemented the new regulatory oversight program, and that has been a tremendous success and, in my view, a program for which all Government agencies that have a regulatory oversight role should look at and basically follow.

This program really focuses attention sharply on safety and is the first step in the path to regulatory reform. The next step, in our view, is to revise the NRC's regulations to incorporate the risk insights and performance-based approaches consistent with those that are used in the regulatory oversight program.

Progress on this second step has been slow but is moving forward, and today the NRC must decide how to treat equipment previously categorized as safety-related but which, with the tools and techniques of today, has proven to have little or no safety significance.

We believe that commercial and industrial standards apply to that equipment. They essentially function the same, but the cost difference and the impact is enormous. For example, an industrial grade 10–horsepower electric motor purchased in commercial grade may cost $350 to $400, but if purchased as a safety-related item that nuclear grade may cost as much as $20,000.

Regarding new plants, we are poised to begin ordering and building the next generation of nuclear power plants, and we as a Nation cannot afford to repeat the problems of the past. In this area, the nuclear licensing process remains essentially untested. Investors need to have confidence that this process will be predictable, reasonable, and consistent.

This is an area, Mr. Chairman, that your committee can help greatly by supporting NRC improving these important processes.

In summary, I'd like to just say that nuclear power plants have outstanding safety records, high reliability, low stable prices, and are critical to protecting the environment. Nuclear is the only large source of electricity that is both emission free and readily expandable. Nuclear energy is also a vital energy source for the future and to meet our Nation's energy needs, and in order to do that your committee's oversight and support of the NRC to continue the changes in regulatory changes are necessary to keep pace with the changing technology and the growth in the marketplace.

Mr. Chairman, that concludes my oral statement. Thank you.

Senator VOINOVICH. Thank you very much.

Mr. Lochbaum.

STATEMENT OF DAVID LOCHBAUM, NUCLEAR SAFETY ENGINEER, UNION OF CONCERNED SCIENTISTS

Mr. LOCHBAUM. Good morning, and thank you for the opportunity to appear before this subcommittee.

I agree with Mr. Colvin on the success of the NRC's revised reactor oversight program, but I'd like to spend my time this morning talking about a few problem areas we think the NRC needs to address in the near term.

Dr. Joe Hopenfeld—retired from the NRC staff last week—had raised concerns about the integrity of steam generator tubes to his management nearly 10 years ago. His concerns are important safety issues, because broken steam generator tubes can cause both the loss of coolant accident and a failure of the reactor containment. This literally can be a deadly combination.

The NRC basically ignored his concerns until an accident last year at Indian Point Two which was caused when a cracked steam generator tube failed. The ensuing public outcry and Congressional attention forced the NRC to finally look into Hopenfeld's concerns.

The NRC asks its Advisory Committee on Reactor Safeguards to evaluate its concerns, and the ACRS reported its findings in February of this year.

In the 10 years since Hopenfeld first raised his concerns, the NRC allowed many nuclear plants to continue operating with literally thousands of steam generator tubes known to be cracked. The ACRS essentially concluded the NRC staff had made these regulatory decisions using incomplete and inaccurate information.

The NRC must really resolve Dr. Hopenfeld's concerns as soon as possible. In the meantime, the NRC must stop making decisions affecting public safety when it lacks "defensible technical bases," as the ACRS concluded.

Two of the NRC's four strategic goals are to maintain safety and to reduce unnecessary regulatory burden. The agency uses plant-specific risk studies to draw a nice clean line between what is and what is not necessary burden.

The UCS released a report last August detailing serious flaws in these risk studies. For example, we compared the risk study results for three sets of identical plants and found that they varied widely, not because the risk at the plants varied that widely, but because the methods, assumptions used in the studies varied widely.

Consequently, it is easy to move that nice, clean line simply by adjusting the inputs and causing a burden to be necessary or unnecessary, as you wish.

The studies we reviewed were nearly 10 years old, but they are the only studies that are publicly available. The previously cited ACRS report on Hopenfeld's concerns suggests that the more-recent studies that are not publicly available are equally flawed; yet, the NRC allows plant owners to reduce the testing frequency for safety equipment and to continue operating with degraded equipment based on the results from these risk studies.

UCS and other groups cannot challenge these regulatory decisions because we lack access to the risk study information. The agency is essentially making regulatory decisions in a vacuum. The NRC must require the that risk studies be corrected and then make the corrected risk study results publicly available.

The pebble bed modular reactor is mentioned as the nuclear plant most likely to be built in the United States in the future. Proponents claim that the pebble bed reactor cannot melt down. Perhaps that is true, but can it catch on fire, as happened in Windscale in 1957 and Chernobyl in 1986? Can plant workers, either by mistake or by design, trigger an accident, as occurred at Dresden Unit 3 in 1974 and Browns Ferry in 1975? Can some unexpected component failure cause fuel damage as occurred at Fermi Unit 1 in 1966?

It appears that the pebble bed reactor achieves its low cost estimates by simply discarding the steel-lined reinforced concrete containment structure that's used at our existing nuclear power plants today. The ACRS has termed this "a major safety tradeoff." A facility like the proposed pebble bed reactor has never been constructed or operated on the planet. Consequently, its expected performance characteristics are highly speculative. It would not be prudent at this time to place undue reliance on the risky technology with unproven safety performance. Nuclear experiments belong in a laboratory, not in our back yards.

Nuclear power plants are inherently dangerous. If nuclear power is to play an expanded role in our future, it is imperative that the NRC become a consistently effective regulator. UCS believes that this goal is attainable, as evidenced by the revised reactor oversight program and the maintenance rule. UCS believes that the agency may require additional resources to meet this goal. Because the NRC is currently a fee-based agency, it may require legislative

changes to supplement the existing resources that the agency receives.

If Congress wants an expanded role for nuclear power, we feel it must provide the NRC with the resources needed for the agency to consistently regulate nuclear power, and must also continue to oversee the NRC with hearings like this to ensure that these reform efforts are successful.

Thank you.

Senator VOINOVICH. Thank you.

Our next witness is Mr. Kingsley.

STATEMENT OF OLIVER D. KINGSLEY, JR., PRESIDENT AND CHIEF NUCLEAR OFFICER, EXELON CORPORATION

Mr. KINGSLEY. Thank you very much, Mr. Chairman, Senator Inhofe. I appreciate the opportunity to speak to you.

I'm going to cover two subjects—it is all in my written testimony—but what we need to do with it currently to improve it and what we need to do to foster the industry going forward.

I thought it would be appropriate to talk a little bit about my background. I have worked 36 years in this business. I've started up, I've managed, I've licensed, I've ran all support, and I've turned around three nuclear programs. I ran the TVA program for some 9 years, ran the entire TVA power program for 3 years, so I have a lot of insight into a number of questions that you've asked. We currently manage the largest nuclear fleet in the United States.

On the current plants we need to continue to focus the NRC on certain key initiatives. We need to build on their recent successes.

I have been quite impressed, having dealt with the NRC for 31 years, what they have accomplished. The reactor oversight process, the renewal of operating licenses, which we will file in the near future on a number of our plants to renew these licenses, and the timely processing of licensing actions, so I applaud that and they do come in on time and on schedule.

On a going-forward basis, we need to continue to focus on regulatory reform. We have just scratched the surface of what's out there. There's still too much bureaucracy, still too much regulation, so the word is "change." And I can tell you from my time at the TVA this can certainly be done.

We need to license this geological repository for our high-level waste. That's very important that we get that done. We need a competitive fuel market. The United States and Richmond Corporation's charges of anti-dumping are simply not valid. We cannot get down to one source of enrichment and we cannot let this industry fall prey to having a monopolistic price control—very important. It's very important we modernize the enrichment facilities in our country.

We also need targeted R&D that supports production, helps us eliminate some of the unnecessary regulation, and is very safety focused.

On a going-forward basis, we need a national energy policy that clearly recognizes nuclear power. There's only really three sources out there. You've got coal, you've got gas, and you've got nuclear, and we play a vital role in that on a going-forward basis.

We are very much behind expanding the nuclear business. We are invested in the pebble bed modular reactor, and we want to bring it to development in this country. There are a number of changes required in order to ensure that the pebble bed can be licensed and operated safely in the United States. First, we need a licensing framework for this new plant. It must include gas-cooled reactors. It needs to be safety focused and risk informed. It needs to address economic impact that the current regulations and laws bring about unnecessary economic impact on this reactor. We need changes in Price-Andersen to accommodate the pebble bed modular reactor. We need changes in NRC fees, which currently on a unit basis where this is a modular reactor, that needs to be changed. And there are a number of other specific issues that need to be addressed, such as operator staffing, etc., to accommodate that.

I mentioned Price-Andersen. We need to renew that, but we also have to have it for new plant development. The older plants will be grandfathered, but it is absolutely a must and we must treat an entire site as a single facility, not an individual reactor.

We also need to continue with the stable regulatory environment that we have. We must exercise a number of unproven policies that are currently on the books—the one-step licensing process, early citing, combined operating license, design certification for the pebble bed modular reactor. And we need to continue this with the same rigor and discipline that the NRC has demonstrated schedule-driven, high-quality product output in some of the positive aspects that they have done that I talked about earlier.

We feel that the cost to design this plant, the pebble bed, should be borne by the investors, but we do feel very strongly that the first-of-a-kind regulatory changes need to either be funded by Congress or some way the NRC needs to absorb this since we are the game in town, we intend to bring nuclear power back.

This concludes my prepared remarks. Thank you very much.

Senator VOINOVICH. Thank you, Mr. Kingsley.

Ms. Jones.

STATEMENT OF MS. GARY JONES, ASSOCIATE DIRECTOR FOR ENERGY, RESOURCES, AND SCIENCE ISSUES, GENERAL ACCOUNTING OFFICE

Ms. JONES. Thank you, Mr. Chairman. I'm pleased to be here today to discuss the challenges that NRC faces as it implements a risk-informed regulatory approach. Implementing such an approach for commercial nuclear power plants is a complex, multi-year undertaking that requires basic changes to the regulations and processes NRC uses to ensure safety. The first challenge is to develop a road map to guide the agency through this complex process.

In March 1999, we recommended that NRC develop a clearly defined strategy to describe the regulatory activities it planned to change to risk informed, the actions needed to accomplish this transformation, and the schedule and resources needed to make these changes.

While NRC developed a plan to address our recommendation, we believe it should be more comprehensive to cover areas such as resource needs, performance measures, or how various activities are inter-related.

One part of the risk-informed approach that has been implemented is the new safety oversight process for nuclear power plants. It was implemented in April of 2000, and the challenge for NRC is to demonstrate that the new process maintains the same level of safety as the old one, while being more predictable and consistent.

The nuclear industry, States, public interest groups, and NRC staff have raised questions about various aspects of the process, including some of the performance indicators selected and the difficulty in assessing activities that cut across all plant operations, such as human performance.

The planned NRC assessment in June after the first year of implementation would be an opportune time to begin to oversee how well this new process is working.

When looking to apply a risk-informed regulatory approach to nuclear material licensees, NRC needs to overcome a number of inherent difficulties. Of most importance, the sheer number of licensees, almost 21,000, and the diversity of activities they conduct, such as converting uranium and using radioactive material for industrial, medical, or academic purposes increased the complexity of developing an approach that would adequately cover all types of licensees.

In addition, the diverse activities of the facilities that produce fuel for nuclear power plants makes it particularly challenging for NRC to design a one-size-fits-all safety oversight process and to develop indicators and thresholds of performance.

In addition, as the number of regulatory agreements with States increases beyond the existing 32, NRC must continue to ensure the adequacy of the State programs, as well as its own ability to oversee licensees that are not regulated by an agreement state. Therefore, NRC will have to assess its staff size, the skill mix, and the location, and the decisions that it ultimately makes on these fronts could have budgetary and other implications for the Agency.

Another challenge for NRC will be to meet its performance goal to increase public confidence in NRC as an effective regulator. This will be difficult because NRC has not defined the target public and does not have a baseline from which to measure the increase.

To address this goal, NRC instituted an 18–month pilot effort to obtain feedback at the conclusion of public meetings. NRC will ask for information on the extent to which the public was aware of the meeting and whether the information was clear and complete. It is not clear, however, how this information will be used to show that public confidence in NRC as a regulator has increased.

As you noted, Mr. Chairman, like other Federal agencies, NRC is challenged to replace a large percentage of its technical staff and senior managers who are eligible to retire. For example, within the Office of Nuclear Reactor Regulation about 42 percent of the technical staff are eligible for retirement. This potentially high attrition could impact license extension and other activities.

The ability to hire and retain staff is compounded by the tight labor market for experienced professionals, and, as mentioned earlier, the declining enrollments in nuclear engineering programs.

NRC has developed a plan to maintain core competencies it needs, and from an overall standpoint, the plan appears to have all

the elements to address the challenges; however, its implementation over the next 5 years will face numerous difficulties, and human capital management is another critical area to watch.

Mr. Chairman, in a sense the NRC is at a crossroads. It is making a major change to the way it regulates safety, and is making this change at a time when marketplace competition is driving decisionmaking on the purchase and operation of nuclear facilities, and with relicensing, potential for new plant construction, and NRC regulation of DOE facilities such as Yucca Mountain, NRC staff are being asked to do more. These are some of the same staff that NRC may lose to retirement.

Given the magnitude of these changes, continued strong Congressional oversight will help to ensure that safety is still the overriding consideration in nuclear operations.

Thank you.

Senator VOINOVICH. Thank you.

Mr. Fetter.

STATEMENT OF STEVEN FETTER, MANAGING DIRECTOR, GLOBAL POWER GROUP, FITCH IBCA

Mr. FETTER. Thank you, Mr. Chairman and members of the subcommittee. I appreciate the opportunity to continue discussions about the appropriate role for the Nuclear Regulatory Commission in the evolving utility competitive environment.

As I've testified before, both debt and equity investors study closely the policies and actions of the NRC when evaluating utilities that operate nuclear facilities. I am happy to say that the NRC's actions since this subcommittee's oversight hearing in July 1998 have been very encouraging. Indeed the united front that the NRC showed today was very nice compared to, I think at the 1998 hearing, there was at least one dissenting opinion at the table that day.

The NRC has allowed stakeholders' input as it has modified its policies to focus on safety-related issues in an objective fashion. Using clear standards based upon individual plant characteristics has allowed the Agency to direct its attention for maximum impact.

Earlier today NRC Chairman Meserve testified about his goals and his colleagues' goals at the NRC. These included: to reduce unnecessary burdens so as not to inappropriately inhibit any renewed interest in nuclear power, and to maintain open communications with all of its stakeholders to seek to ensure full, fair, and timely consideration of issues.

These goals, together with the NRC's support for extension of the Price-Andersen Act, are music to investors' ears. Indeed, far from the refrain that many industry watchers were humming in 1998—that nuclear might be dead in a competitive environment—last week Fitch rated the Exelon Generation Company—Mr. Kingsley's non-regulated generating company that has 17 nuclear plants—at triple-B-plus, a very respectable investment grade rating.

Finally, let me mention the elephant in the corner—the disposal of spent nuclear fuel. Choosing and developing a permanent site for the disposal of spent fuel is a necessity. Before we see progress on planning for the construction of a new generation of nuclear plants, the waste issue must be resolved. Any delay in achieving this goal

likewise delays the ability of the nuclear industry to assist in the country's future electricity needs.

Thank you.

Senator VOINOVICH. Thank you very much.

We have been joined by Senator Corzine from New Jersey, and Senator Corzine is pretty fortunate in that 70 percent of the power in his State is generated by nuclear power, and so he is pretty familiar with the benefits of it.

Senator Corzine, do you have a statement that you would like to read before we ask for questions?

Senator CORZINE. I'd just ask that it be put in the record.

It is actually 50 percent but it is an important part of our energy sources, and we have a major medical investment, as well, that it is a very keystone research effort on it.

I'm excited about getting myself informed, and I very much appreciate the panel's efforts. I apologize for not being here. As I'm sure you've heard, we've had multiple hearings this morning and votes. But I intend to study your testimony and I appreciate very much this hearing, Mr. Chairman. It is a terrific effort that needs to give us all a framework to actually debate these in an intelligent way.

[The prepared statement of Senator Corzine follows:]

STATEMENT OF HON. JON S. CORZINE, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Thank you Mr. Chairman.

Mr. Chairman, the issues before the committee today are extremely important to the people of New Jersey. My State has four nuclear generators, and together they represent approximately 50 percent of the electricity generated in New Jersey.

NRC regulation of these facilities therefore has important implications for the New Jersey economy. Other uses of nuclear material, such as nuclear medicine, are also important to my constituents. As a result, I am concerned that NRC regulation be as effective and efficient as possible.

More importantly, however, I am concerned about safeguarding public safety and the environment. Changes in NRC regulations should not unduly compromise these goals.

I believe that science and common sense can and should guide the NRC's balancing of safety and efficiency. "Risk-informed regulation" is the stated underpinning of the NRC's efforts to modify its regulations. This phrase "risk-informed regulation" sounds appealing, and may hold the promise of a proper balance. But the issues are complex, and I want to learn more about how the NRC is proceeding.

So I look forward to the testimony of our witnesses. I am particularly interested in their assessments of the validity of the approach that the NRC is employing in developing "risk-informed regulations." Within this issue, I am most interested in hearing the panelists' perspectives on the new reactor safety oversight process. With that, Mr. Chairman, I conclude my remarks.

Senator VOINOVICH. As the panelists know, I am very committed to seeing if we can increase the productivity of the current existing facilities and to go forward with new construction of new facilities.

I would be interested to—Mr. Lochbaum, you have been watching it and you mention in your testimony that you are concerned also about the staffing capability in terms of paying attention to the safety aspect of this, and that's really important, because, you know, one bad accident and here we go again.

I assume your organization is not opposed to nuclear power?

Mr. LOCHBAUM. No. We basically sit on the fence. We neither think it is the best answer for the future, we're also not anti-nuke,

so we get shots from both sides. The benefit is we get twice as much practice ducking.

[Laughter.]

Senator VOINOVICH. Twice as much what?

Mr. LOCHBAUM. Practice ducking.

Senator VOINOVICH. Yes. But you are concerned about that, and it just seems like it is across the board. I guess the point is that we are interested in having the people that can process the applications, and so on and so forth, but we are also interested in making sure we've got the people that are going to go out there and make sure that the safety aspect of these things is stayed on top and we don't get careless with that. That would be a disaster for everyone.

The question that I would like to ask is Mr. Fetter. To build a nuclear power plant or even to maybe put some stuff in to increase its capacity costs money, and usually companies come to Wall Street and ask for money.

Mr. FETTER. Sometimes.

Senator VOINOVICH. Sometimes. Assuming that the people that are going to move forward to build some more of these facilities—you know, we create an environment for that to happen—I'd like you to re-emphasize how important it is in terms of the decision-making in terms of what we do with this stuff. It has been around.

It has been around—as I mentioned in another hearing, I was the County Commissioner in Cuyahoga County in 1977 when they talked about storing nuclear waste in the salt mines under Lake Erie, and at that time I wasn't real enthusiastic about that, and we've now moved to Nevada and Yucca Mountain, but tell us about that. How important is it that we get this thing over with? And if we don't, what impact do you think it's going to have in terms of you guys looking at it?

Mr. FETTER. Well, I think that before there's going to be financing for a new generation of nuclear plants, the spent fuel issue has to be resolved. Certainly, based upon the comments of Senator Reid this morning, he has an interest in the proceedings at Yucca Mountain.

From Wall Street's point of view, a resolution must be found, and if Nevada is the best place, then it may have to be chosen over the objections of elected officials in that locale. If Nevada is not the right place, then the Congress and the Administration should move forward and find where that better location is, because there will not be another round of nuclear construction until that issue is resolved.

Senator VOINOVICH. Ms. Jones, you have—GAO has looked at it, and you really believe that the NRC has done the work necessary to determine the number of people and quality of individuals they have to do the job that they have to do now and in the future, assuming more licensing, perhaps new facility? Do you think they nail that down?

Ms. JONES. What we've looked at, Mr. Chairman, is their overall plan and what compared it against GAO's framework that we came up with because of the human capital problems across Government. We looked at it from the standpoint: does it have the elements of strategic planning? Is it looking at succession planning? Is it looking at having the right performance culture?

So, from a very broad brush, without looking at the specific details behind it, it does have the right elements in it. But whether or not it is going to do the trick, I think only the implementation of it over the next 5 years will tell. It is going to be very critical for us to watch.

Senator VOINOVICH. OK. So they've got the plan. Your concern is are they going to be able to implement the plan in terms of retention and attracting people to the agency?

Ms. JONES. Correct. Will they carry through the plan that they've put in place? Will they really define the mission needs that they have, the skills and abilities, and then have a plan in place to get those people?

As you and others have mentioned, there's a lot of outside factors that are going to make it more difficult for them to even carry out their plan.

Senator VOINOVICH. Now, do you just work at the NRC or do you kind of go from agency to agency to look at this issue?

Ms. JONES. GAO has looked at it across the Federal Government, and I think, Senator, as you are aware, GAO has said that human capital management is a high risk area for all the Federal Government at this point in time.

Senator VOINOVICH. Right.

Ms. JONES. It is really critical because it is going to impact other agencies' ability to get their missions done in an effective, efficient way.

Senator VOINOVICH. Well, as you know, we're working with Comptroller General Walker on this and many other people——

Ms. JONES. Absolutely.

Senator VOINOVICH [continuing]. To give it the high profile it needs and do something about it, but the question I have is: has GAO gone into all of the other Federal agencies and done the same thing that you're talking about today to see if they have a plan in place to deal with their human capital crisis, or is it just the NRC that's out in front?

Ms. JONES. We have done it in some agencies, Senator Voinovich, not for all. For example, we've done some limited work at the Department of Energy looking at their Defense labs and what plans they have in place to address some of the same kinds of challenges the NRC has for technical staff. But in terms of doing a very detailed analysis of every Federal agency, no, we have not. We've done it for some and are doing it for others now.

Senator VOINOVICH. Well, with my other subcommittee chairmanship hat, I would like if you can go back to the Agency and ask them if they could give me a little report on the status of those agencies that they have reviewed, like you have with the—I'm delighted to hear that you've done that, because one of my concerns with—and I've talked with Shawn O'Keefe or with Mitch Daniels—is, you know, have those agencies even looked at where they're vulnerable, and what you're saying to me is in the case of the NRC they have done that.

Ms. JONES. NRC has begun to do that and they do have a plan in place, and from a very broad brush they have the right elements in the plan. I think we probably would want to look at the details

behind it to make sure that they have all the I's dotted and the T's crossed.

Senator VOINOVICH. Yes.

Ms. JONES. But we'd be happy to get back with you on the other agencies.

Senator VOINOVICH. Thank you.

Senator Inhofe.

Senator INHOFE. Thank you, Mr. Chairman.

Mr. Colvin, it seems as if, in the last short period of time, there have been a lot of favorable press on nuclear energy relative to a few years back. I just wondered what you would attribute that to.

Mr. COLVIN. Senator Inhofe, I think as we look across the problems that our Nation faces in energy, and whether it be in electricity, in gasoline prices going up, in providing home heating oil and natural gas over the last winter, I think we're seeing a recognition of the important role that energy plays in our economic growth, and that resonates with the individual member of the public.

We've seen that really come about in nuclear energy. I think, to digress just a moment, the industry really has seen support, public support in the area of two-thirds of the public for many, many years supporting the use of the technology. That has been somewhat unwavering over time. What we have seen, however, is a change in that as people recognize the energy needs and the recognition of the need to, in fact, build more nuclear power plants or expand our use in this technology.

For example, in polls that we ran last year and the year before, we saw 24 to 30 percent increases in support for use of nuclear technology across the United States, probably more in the west. Just as an example, in California and the western States, in October 1999 we had about one-third of the public supporting nuclear as compared to the rest of the country. In March of this year it was 62 percent in the west supporting nuclear. So, as people see the importance of energy as they, in fact, lose the opportunity to have electricity for even short periods, it brings that home.

We've just done some other public opinion research that will be released. Later today I will be happy to share that with the committee. But really, I think the public recognizes that 10 to 20 years in the future that the major source of electricity in the United States from a fuel source perspective from the public's view would be nuclear followed by solar.

Senator VOINOVICH. Yes, and I think we're all concerned about alternative sources and efforts are taking place right now, but I would feel—you know, we went through several years of problems with ambient air and all that and the public was kind of made aware that there are some problems there, and all of the sudden they say, "Well, in this area there isn't a problem. CO_2 is not an issue." Mr. Colvin. Yes, sir. That's correct.

Senator VOINOVICH. But, Mr. Lochbaum, you say that you're on the fence so everyone can shoot at you. I'll go ahead and do that.

If you don't use nuclear and expand nuclear, what are the choices out there, because, in terms of today's science, we know it works. We also know about coal. We know about natural gas. But when you add it up as to the needs that are there, and not just

the potential problems but existing problems, you know, you take that into consideration as to—what are the choices now.

Mr. LOCHBAUM. Our organization, along with several other environmental organizations, has done a number of studies in the last 3 to 5 years looking at meeting energy needs as projected by the Department of Energy and what resources are available today to meet those needs, and what the conclusions consistently show is that increased reliance on renewable energy technologies—fuel cells, biomass, wind power, solar power, and so forth—can meet those needs with—an assumption we make in those studies is that the existing fleet of nuclear power plants runs to the end of their operating lifetimes.

Senator VOINOVICH. Well, you talked about the 10 years, your risk studies are 10 years old, and then you painted a pretty bleak picture on some of the steam pipes rupturing and this type of thing. Mr. Kingsley, would you like an opportunity to respond to some of the statements that were made by Mr. Lochbaum in his opening statement?

Mr. KINGSLEY. Yes, I would, Senator Inhofe.

First, on the steam generators, we have very thorough inspection programs. We have very good emergency operating procedures to handle any of that. We have early detection techniques that allow—so we believe that all of our steam generators are very safe, they are operated safely. Our operators are trained to handle that.

With respect to the pebble bed modular reactor, there are some technical issues that we are in the process of resolving.

Senator VOINOVICH. Could you just tell me what pebble bed is? I mean, we've heard it, and I probably should have picked it up from reading, but what is pebble bed?

Mr. KINGSLEY. It got its name, Senator, if you were to imagine a very, very large number of ceramic balls about the size of a pool ball where you've got small chips of uranium in a ceramic there, and that's in what we call a "reactor." Helium gas passes through this, and so that's where you get the "pebble bed" out of that. The helium gas is heated and that goes on over.

Senator VOINOVICH. Science. OK.

Mr. KINGSLEY. Yes, we won't go into it any further detail.

Senator VOINOVICH. It's not Pebble Bed, California.

Mr. KINGSLEY. Right.

Senator INHOFE. Is that all cleared up?

[Laughter.]

Mr. KINGSLEY. It's a little more than a pebble.

Senator VOINOVICH. Are there other questions on that?

Senator INHOFE. Well, let me ask a question of Mr. Fetter over here. When we had our brownfields hearing, my major concern is, all these people going out and talking about the different ramifications of it, if you don't have something, a product that the contractors will bid on, then it's not going to make any difference because they're not going to bid. I came from that segment of industry and I know that if there are too many uncertainties they won't do it.

The same I'd say is true with you. If there aren't investors out there that are going to look at the risks and make their evaluations and put their money into the construction of new nuclear plants,

then it doesn't make any difference what we're talking about here, there aren't going to be any.

So I'd like to ask you, I think you inferred in your testimony that the market is much better now than it was a short period of time ago, and what do you look for in the future for that?

Mr. FETTER. I think just what we're seeing in California. In my testimony I noted that 3 years ago at the time of the first hearing, nuclear didn't have a place and California was held up as the model for the future. I think the problems we're seeing are a lack of supply for the demand that's growing, and there is clearly a need for more electricity. If it comes from nuclear power, there will be investors to provide for construction, but only if the uncertainties that you referred to get cleared up.

I said the biggest uncertainty is spent fuel. There are other uncertainties that are mentioned throughout the testimony. But investors are interested in making money. The more uncertainties that are laid on the issue, the less interested they will be willing of taking that chance.

Senator INHOFE. And the higher the rates go, and that's ultimately passed on.

Mr. FETTER. Yes.

Senator INHOFE. If they are successful.

I know my time is up, but I want to ask just one more question of Mr. Fetter.

You talk about the triple-B-plus rating of the 17, I guess, plants that Mr. Kingsley has. Now, I also come from the insurance industry. I know what a Best rating is, but I'm not sure I know how this—what a triple-B-plus rating is.

Mr. FETTER. Well, the rating scale would be triple-A, double-A, A, then triple-B.

Senator INHOFE. As in bonds?

Mr. FETTER. This would be bond rating.

Senator INHOFE. OK.

Mr. FETTER. And triple-B-plus is well into investment grade.

Senator INHOFE. Yes. Thank you.

Senator VOINOVICH. Senator Corzine.

Senator CORZINE. Given that the spent fuel issue is such an overwhelming concern, are there other models—maybe you all talked about this in your testimony—but other models in other countries that are much more committed to nuclear energy as a source that we could learn lessons from more diffuse than going into one site? Does anybody want to comment on that?

Mr. COLVIN. Senator, Joe Colvin here. I'd be happy to at least start that discussion.

First of all, in any technology such as nuclear we have to protect the waste from the environment for many, many years. In this case, those years are a little longer than perhaps some other types of technology, but we manage that waste and have managed that waste well and protected it from the environment. The challenge that we have today is to move forward and dispose of that waste byproduct for many, many years into the future.

There is a lot of cooperative sharing that goes on between various countries, but ultimately, no matter what process, whether you reprocess, recondition the fuel, or reuse it such as the French

and the Japanese are doing, or use a once-through fuel cycle such as we're using in the United States, ultimately you have to have a repository or a place to store the waste byproducts, and that is a deep geologic repository.

Senator CORZINE. The French reprocess the fuel, though?

Mr. COLVIN. The French have chosen to reprocess the fuel, and they take the fuel out of the reactors, reprocess it, put the usable product back into the new fuel and put it back in the reactors, and they do that typically two to three times before that is no longer usable.

Then they take the remainder of that waste byproduct and they plan on ultimately putting it in some type of deep geologic repository to protect it for the environment for many, many years. Our choice was also geological repository, and that's what is being studied. It's being studied at Yucca Mountain. The Department of Energy issued their science and engineering reports last Friday and have begun the process to move forward to a recommendation for suitability, which is scheduled to occur some time in the latter part of this year.

Senator VOINOVICH. It's my understanding, too, isn't there—they're contemplating building one of these deep depositories in The Netherlands someplace?

Mr. COLVIN. Yes, sir. That's correct. I think each of the countries that is looking at this has used the technology as looking at, in fact, some type of deep geologic repository. The Fins and the Swedes, for example, have decided that they will emplace this in the bedrock underneath the Baltic Sea. That turns out to be a place that they've evaluated. In the United States we studied many sites—salt deposits, granite deposits, and ultimately volcanic tough, which is the Yucca Mountain site, and the process went through and chose the Yucca Mountain site for a determination of suitability. So there are many different processes that are being looked at by the various countries.

Senator CORZINE. We have a dispersed system now, though. If I understand correctly, in New Jersey they actually store the spent fuel at the site. Is that not a long-run acceptable format for dealing with spent fuel? Is it one option?

Mr. COLVIN. Well, I think in the storage of spent fuel we have to go back to 1954 and the Atoms for Peace program made the decision, as a Government policy, that the waste from these reactors would, in fact, be the responsibility of the Government, although the industry that would use this would pay for this technology. And so as these plants were designed, they were designed to store the fuel in a wet storage inside the fuel pool for a number of years that was sufficient to allow the fuel to cool off, and then to have the Government take that fuel and put it in a deep geologic repository, and that was the plan. That was the plan starting in 1954 and, in fact, the Department of Energy had the responsibility to begin accepting that fuel in 1998.

Since the DOE could not meet that commitment for a number of reasons—which we could discuss, I'm sure, at length—and that's the process that is ongoing, then the companies had to take some alternative action, which was, in fact, to expand to a dry cast storage at those sites.

The NRC has testified and the National Academies have looked at this issue in depth, and their reports indicate that the safest and most responsible way to manage this waste byproduct is to move it from the 60 or 70 locations in 31 States to a centralized facility at the site where the permanent repository is going to be operated, and that's the process that is in place and moving forward today.

Senator CORZINE. Thank you.

Senator VOINOVICH. Senator Corzine.

Senator CORZINE. I'd go to Mr. Fetter in one sense. Has there been a lot of debt issuance to support the industry? When I left the bond business about 2 years ago, you couldn't raise any capital?

Mr. FETTER. I mean, certainly, as we mentioned with regard to Exelon, Amaren, and PSE&G Power, there is support for nuclear-owning generation companies, and so the mood has very much changed in the 2 years since you left.

Senator VOINOVICH. OK. Any other things?

Senator CORZINE. No, thank you.

Senator VOINOVICH. I'd like to have the panel's comment on two things. Following up on Senator Corzine's question about Yucca and deep geological, can anybody bring me up to date on, if it was approved, how long would it take? And it's my understanding there's some talk about a temporary facility in Utah to hold this material until it is ready to go to Yucca Mountain, assuming Yucca Mountain is approved. That's one question.

The second question deals with one, Mr. Kingsley, you mentioned, and I am real interested in what's going on with USEC. I've followed that one since I was Governor, and I read recently—I think it was yesterday—in the paper that the issue of they are negotiating a contract with Russia, who is now sending us their uranium, and USEC claims they are paying too much for it, and there is a glut of uranium on the marketplace today. Your thoughts on whether we have an adequate supply if we're going to move forward, and, if it isn't adequate, how do we make sure it is adequate and who ought to run it? Maybe we will start with that one for you, Mr. Kingsley, and we'll follow up with Mr. Colvin or anybody else that wants to comment after Mr. Kingsley.

Mr. KINGSLEY. A couple of issues. One of the big advantages that we have in operating nuclear power plants is our fuel. Typically, the fuel costs about $4.50 per megawatt hour, and it has been extremely stable.

Senator VOINOVICH. That's $4.50?

Mr. KINGSLEY. Yes, $4.50.

Senator VOINOVICH. As compared to coal, which is about $1.50, right?

Mr. KINGSLEY. That's exactly right.

Senator VOINOVICH. OK.

Mr. KINGSLEY. And that has been increasing markedly lately in coal, particularly with the shift in the market to the Powder River Basin coal with that.

So what we want to ensure is that—and we strongly believe that enrichment is a service. We own the product, and we can obtain enrichment on the world market, so that's at the key of this issue.

Second issue that's also tied in to the fuel is that, with the nonproliferation and the disposal of some of the highly enriched ura-

nium, that with that coming in and with USEC being a sole agent, we don't want to be subject to what they might charge for that uranium, blending it in. So that's the principle. We want to protect a great advantage that we have, and that's why we are very active in pursuing this with Department of Commerce.

Senator VOINOVICH. You do not want to be the captive. Who else besides——

Mr. KINGSLEY. We do not want to be captive. There are two suppliers from Europe, Urenko and Cogema, that we obtain some of this from. There's a charge by USEC that they are dumping on the market here in the United States. They've had government subsidies. So we want to protect the fact and actually have a very competitive environment.

We also believe that there's a need to modernize the enrichment facilities. Those were built a number of years ago back there in the World War II times as a part of the atomic movement at that time.

Senator VOINOVICH. But USEC is the only one in the United States that does it?

Mr. KINGSLEY. They are the only ones that do that. That's correct.

Senator VOINOVICH. And you are concerned that they wouldn't, through some type of legislation, keep out competition?

Mr. KINGSLEY. That's correct.

Senator VOINOVICH. Are you concerned if—let's say USEC goes out of business. Would you argue that the Federal Government should take it over and that we do have some——

Mr. KINGSLEY. We do need an enrichment source here in the United States.

Senator VOINOVICH. You'd never get to a situation where——

Mr. KINGSLEY. No. Absolutely not.

Senator VOINOVICH. Got to have it?

Mr. KINGSLEY. Got to have it. Need to have it.

Senator VOINOVICH. For economy and for our national security?

Mr. KINGSLEY. Right. Otherwise——

Senator VOINOVICH. If USEC goes under, the Federal Government or somebody ought to take it over and make sure we can keep it going?

Mr. KINGSLEY. Absolutely. Yes, sir. Look where we stand on imports on oil and everything. We could be in that same situation. We don't want to get caught up in that.

Senator VOINOVICH. OK. Now we've got the fuel, Mr. Colvin. We've got to get rid of the waste.

Mr. COLVIN. Yes, sir. Mr. Chairman, if I understood your question, it had to do with the time to actually make the repository operational and also the private fuel storage initiative.

The schedule that the Department of Energy has underway is to try to come to a decision on suitability, a recommendation by the Secretary of Energy and a recommendation to the President for Presidential decision some time around the end of this year. If that decision was positive, that triggers a number of steps with the State of Nevada and ultimately brings the issue, assuming Nevada's challenge, back to the Congress for a vote to override the veto of Nevada.

Once that process is beyond us, some time likely in the middle of next year, then the DOE would submit a license application to the Nuclear Regulatory Commission for processing and start that process. From that point until the time that the repository is in full operation is somewhere between 2010 and 2015, so we are on a very long timeframe schedule to actually have a repository that would be in full operation.

Senator VOINOVICH. What about the temporary thing I just mentioned in Utah?

Mr. COLVIN. A number of the utilities, given the fact that we have not had the Government meet its obligation to move fuel off the reactor sites, have been working on licensing of a private fuel storage initiative in support—this is supported by the Goshute Indian Band in Utah, and this is a completely private initiative paid for by a number of investors to license and bring into operation a facility to, in fact, act as a relief valve, if you want, on plants and companies that have run out of fuel storage and that are under pressure from their State and local governments to, in fact, move that fuel out of their State and off of their site. So that is in the process of being licensed currently by the Nuclear Regulatory Commission, and I expect that that will move forward.

Senator VOINOVICH. So that's like a temporary—where some of them don't want to store it at their place of business, they would then send it out there and put it in a holding pattern until the other thing is built?

Mr. COLVIN. Yes, sir, that's basically it. And it would be in the dry form—form of dry cast storage, above-ground storage that, in fact, we see at some of the power plants that have run out of space in their fuel pool storage today.

Senator VOINOVICH. One last question, to follow up with Mr. Fetter. What is the key thing that you are going to be looking at? We know that if the NRC says it is OK, Nevada will do everything to say they don't want it. I guess you say then it comes back to us for a vote, and if then we vote to override their veto, then it becomes a reality?

Mr. FETTER. That's correct.

Senator VOINOVICH. Is that the thing that would trigger Wall Street to say, "Hey, this is going to happen?"

Mr. FETTER. Well, it would be that. I guess litigation would follow that. And so at some point, after all the litigation is done, then Wall Street pays more attention.

If I can make a comment about Senator Corzine's statement, you raised the concept that if spent fuel is stored short-term now at the plant sites, you wonder whether that could solve the political issue longer term. It would seem to me that the three issues that are being explored with regard to long-term storage are long-term safety and health issues, physical security issues, and then the political issue. Those are what are being fought out.

I think if you resolve the political issue by storing it at either one site in each State, or 50 sites, or at each plant, so you'd have over 100 sites, long-term, you might solve the political issue, but the other two issues would be much worse off than finding one site somewhere in the United States to do it.

Mr. KINGSLEY. And that would be just short term, I might add, too. Eventually we'd decommission and we're going to have to move this fuel offsite.

Ms. JONES. And also we've found in the low-level waste program that we haven't been able to find States to host sites. States do not want a site, even low-level waste, so I think the point of finding locations in several States for high-level waste would be very difficult.

Senator Voinovich, I also wanted to make a point on the USEC question that you had earlier. I think USEC at this point in time is in conflict because they have two roles. One role is they are acting as the agent for the U.S. Government in a non-proliferation program. That's the reason that they are buying the enriched uranium from Russia. And they're also trying to run a competitive market company. And I think that at times these two roles are in conflict, and that's one of the reasons they're running into the monetary problems they're running into.

Senator VOINOVICH. Right. I think everybody knows the largest amount of money that we give Russia every year is this contract that USEC has. I think it is, like, $450 million a year or something.

Mr. LOCHBAUM. It's huge.

Senator VOINOVICH. It's a huge amount of money.

Senator Inhofe.

Senator INHOFE. Mr. Chairman, I'm glad we had this discussion, Mr. Kingsley talking about his recommendation should we find—you know, we went through this thing. I can remember when Don Hodel was Secretary of Interior in 1987. We went around the country and tried to explain to people what a crisis it was from a national security standpoint that we were becoming more and more dependent upon foreign sources for oil, and not an energy problem but a national security problem. I think now people are aware of that. Back then it was below 38 percent dependency. Now it is approaching 60 percent.

I don't want to get ourselves positioned where we might be facing that same problem in nuclear energy. I think that's very, very significant that we're doing this.

I think it is a really appropriate time, Mr. Chairman, to have this committee hearing because we are on the verge of receiving a national energy policy, and I, Senator Corzine, as a partisan Republican, let me tell you I'm just as upset with Republicans as I am with Democrats. I remember when President Reagan was President we went in to plead our case as to why we should have a national energy policy, and then when Bush, Sr., was elected we thought, surely, coming out of the Midland Texas oil fields he'd agree with that, and he didn't do it. Of course, Clinton didn't do it. So now we are at the point where it is going to be done, and I can assure you all the indications are there and the statements made by the President and the Vice President that nuclear energy is going to be a very prominent part.

So we're right at that point now and it is the appropriate time to be trying to resolve these problems.

Senator VOINOVICH. Senator Corzine.

Senator CORZINE. May I ask Mr. Fetter what is the next big risk issue aside from spent fuel? I'm under the impression that liability insurance is pretty hard to get.

Mr. FETTER. The Price-Andersen Act extension would be very important. I think we will also watch how Exelon and other companies operating as non-regulated generating companies that have a portion of their supply from nuclear power, how they operate. As you know, with nuclear there are many things to watch, but certainly over the past 5 years it has been a much more positive story, and so I think Wall Street is much more comfortable with the issue.

Senator CORZINE. But we are going to have to reauthorize Price-Andersen?

Mr. FETTER. Yes.

Senator CORZINE. All right. Let me ask just another sort of—I'm curious. Are there other sites other than Yucca Mountain that were close that were not chosen as the site of ideal location but met the terms and conditions that people who would make judgments about where spent fuel should go were identified?

Mr. COLVIN. Senator, yes, sir, there were. In 1982 the Senate and the Congress passed the Nuclear Waste Policy Act of 1982, and that began the process. The Department of Energy evaluated a number of sites in the United States. I don't remember the exact number, but there were tens of sites that were screened, maybe even more, and they came down ultimately to propose a characterization or review of three specific sites.

The cost for that evaluation became very, very significant, and in 1987 the Congress amended that act with the Amendments Act of 1987 and selected the single site at Yucca Mountain for characterization and suitability.

Since that time, through that process, we probably know more about the "ologies"—the hydrology, the meteorology, the geology, the seismology, and so on—of that place better than any other place in the universe, and that is the site, the place that has been studied.

Now, whether there are other sites that might be available should that site fail, that would have to be restudied and reevaluated given the technologies and the science available to us today that we may not have had, say, 20 years ago.

Senator CORZINE. Ballpark figure on how much that study would cost?

Mr. COLVIN. I really don't know in today's dollars. The current life cycle cost of the program is about $56 billion. Ratepayers and utilities have paid in about $16 billion, and we've spent about half of that in studying this one site, if that kind of gives you at least a feel for the amount of money.

Senator INHOFE. Yes. Mr. Chairman, one last question.

Senator VOINOVICH. Go ahead.

Senator INHOFE. You touched on this, but if it ends up going through the process where it is going to be Yucca Mountain, what would be—in coming back and going through the steps that you just outlined in response to the chairman's questions, what would be the timeframe that that would be finalized? And, second, if that is for some reason rejected and we had to go into this other alter-

native, I'm equally concerned about when as I am how much. So about how much longer would it take if you were—if somehow Yucca was rejected in this process?

Mr. COLVIN. Senator Inhofe, I really don't have a good estimate on that, but I think that if the Yucca Mountain process, after the detailed scientific studies and engineering analysis, would show that that site was not suitable for a deep geologic depository, we'd basically be back at square one. I think we'd have to go back and start this process anew, because, I mean, after we've spent all that time and all that energy and all that scientific review with the best minds that we have working on it, I think we'd really be back at the beginning.

Senator INHOFE. I think that should be determined, and I think—Ms. Jones, do you have any comment about that, or would you be able to try to analyze that scenario and then for the record get back with us and let us know a time line that it would take in the event that we had to reject the Yucca site.

Ms. JONES. We could certainly do that based on kind of historical data about what has happened with Yucca Mountain.

Senator INHOFE. Yes.

Ms. JONES. But I would agree with Mr. Colvin that we would be back to square one and have to look at one of these other sites from the very beginning.

Senator INHOFE. Well, I do think it is necessary for us to have some type of an idea, though, so if you could help us with that we'd appreciate it.

Ms. JONES. We'll try to do that, Senator.

[The information referred to follows:]

NUCLEAR WASTE REPOSITORY TIME LINE

1977	United States Geological Survey recommends that DOE consider the Nevada Test Site as a potential host for a mined geologic repository for disposal of high-level nuclear waste.
1980	Yucca Mountain, on the western border of NTS, is selected for eventual study as a potential repository site.
1981	DOE formally decides on mined geologic disposal for spent nuclear fuel and high-level radioactive waste.
1981	Nuclear Waste Policy Act of 1982 enacted.
1986	President approves DOE's recommendation to characterize (investigate) three candidate sites for the first repository (Yucca Mountain, Nevada; Hanford, Washington; and Deaf Smith County, Texas) as well as the cancellation of the program to screen and select a site for a second repository.
1987	Nuclear Waste Policy Amendments Act of 1987 enacted. Yucca Mountain becomes only site authorized for characterization by DOE.
1988	DOE issues Yucca Mountain Site Characterization Plan.
1991	DOE establishes major acquisition cost, schedule, and technical baseline for developing a repository at Yucca Mountain by 2010.
1991	DOE receives environmental permit from the State of Nevada and begins site characterization.
1999	DOE issues draft environment impact statement for a repository at Yucca Mountain.
2000	DOE issues notice of beginning of public comment period leading up to projected decision by the Secretary of Energy in December 2001 on whether the Yucca Mountain site is suitable for a repository.
2003	If Yucca Mountain is selected as a repository site, DOE would submit an application to the Nuclear Regulatory Commission (NRC) to construct the repository.
2010	DOE expects to receive a license to operate the repository from NRC and to receive the first shipment of spent fuel to be disposed of in the repository.

Mr. KINGSLEY. I can tell you from a cost standpoint on the operating side that you go out about 10 years, and then your costs go up markedly, you know, with having to store onsite that we talked about earlier, so it's going to hurt our economic viability.

Senator VOINOVICH. That's a tough one. I know when we were in the regional low-level waste disposal thing and when Michigan decided they wouldn't to it, Ohio picked up the responsibility, and I think I spent 3 or 4 years on just trying to find a site in Ohio to try to do low-level radioactive waste, and it is just incredible. It just would go on and on. I figure low-level, that's 4 or 5 or 8 or 9 years, so I think your point is well taken that if that isn't the case then we really have a serious problem on our hands.

In my opening statement I said, "If we are serious about protecting our environment and providing safe, reliable, and affordable electricity to all Americans, then we need to improve how we burn fossil fuels, promote efficiency, increase the development of nuclear energy for today and for the foreseeable future. We also need to continue investing in renewables such as solar and wind to make them cost-effective and feasible, not for today or for tomorrow but for use at some point in the future." One of the things that I keep running into in the Senate—and if any of you have anything written that you could help me—is that there is this attitude here that somehow through conservation, through fuel cells, through solar, through wind, through water, and so forth, all these other things, that somehow we're going to be able to deal with the energy problem that we have in this country. I'd like some information on that, because it seems to me that some people are denying the fact that we've got all this stuff that's out there and we have made progress but put it all together, all the research, all the stuff that we've got, with the demand that we've got and where we are with some of those other things, that if we don't have more nuclear power, if we don't use clean coal technology to burn coal, if we don't look at some of the refining capacity and all the other stuff that needs to be done, we are going to be in deep, deep trouble economically and from a national security point of view.

If any of you have got anything on this——

Mr. KINGSLEY. We'll be happy to submit on that, Senator. And I can tell you unequivocally we do need research in some of these areas, but if it is not with nuclear or if it is not with clean coal or if it is not with natural gas, we are not going to be able to meet this growth. We're growing something like 2 to 2.3 percent in the greater Chicago area. We have similar growths in the greater Philadelphia area. We have to add these sources in order to meet that load.

We are also faced with the fact that a lot of the coal plants are very, very old, and so these plants are going to have to be refurbished.

So there's only three games in town, and you cannot get there any other way, but we'll be happy to give you something on the record about that.

Senator VOINOVICH. Thank you.

Mr. COLVIN. Senator, I'd be happy to provide some of that input, also. I would just give you one data point from last year's electricity generation. The total amount—as much as we need solar

and wind energy, and we ought to move forward in that direction—and we clearly support that—the reality is that they generated less than .1 percent of the total generation in the United States.

To put that in perspective, the total amount of wind and solar in the United States last year was the equivalent of the electricity needed to operate three New York City subway systems. I mean, that's the amount of electricity that we're talking about as this demand is growing, so we have to look at it realistically.

I agree with Mr. Kingsley's comments that we really have to put our focus on our proven sources of electricity to meet the economic growth to support our economy.

Senator VOINOVICH. Senator Carper has joined us. Senator Carper, would you like to make a statement or ask a question? We're glad you are here.

OPENING STATEMENT OF HON. THOMAS R. CARPER, U.S. SENATOR FROM THE STATE OF DELAWARE

Senator CARPER. Thanks so much. I'm delighted to be here, and I welcome all of the witnesses. It is nice to see you, each of you, and we appreciate your sharing your time and your thoughts with us.

I've mentioned to some of our colleagues earlier this year I took a bunch of Boy Scouts from Troop 67 just north of Wilmington, Delaware—my sons are in that troop—and we went down to the Norfolk Naval Station—being an old Navy guy—took them down for a weekend, slept in the sailor's barracks and ate in the galley and then we went and visited ships and submarines.

One of the ships we visited was the *U.S.S. Teddy Roosevelt*, a nuclear-powered carrier, about 1,000 feet long and 25 stories high, and it carries about 70 aircraft when they're underway, about 5,000 men and women when they are underway with the air wing aboard.

For me, most interesting of all, it needs to stop to refuel once every 25 years—once every 25 years.

Now, I actually raised this and shared this with my colleagues at a Democratic caucus we had back in February or March, and I said, "You know, we really can't foreclose—as we consider alternative forms of energy, we can't foreclose the need to find more efficient, more effective, safer ways to create nuclear power." I thought a few of my colleagues immediately labeled me with a new nickname, "Radioactive." Some of the kinder ones, by the way. God knows what the others are saying.

[Laughter.]

Senator CARPER. But I simply feel that there is some potential here, and I think there's potential for creating nuclear power in ways that are safer.

One of the big issues we hear about, citing nobody wants to have a nuclear power plant close to their home, or relatively few people do. We hear about what do we do with the waste, what do we do with the waste. And I just want us to focus on what do we do with the waste, and in terms of recent research that you may have addressed in your testimony that, I'll be honest, I just haven't read, or with respect to what's going on in other countries.

If nuclear power is going to play a somewhat greater role in our future to help us meet our energy needs, what do we do with the waste? And whoever on this panel would like to help me with that, I'd welcome your thoughts.

Senator VOINOVICH. Senator, we'll have them to give a summary. We spent about the last 20 minutes talking about——

Senator CARPER. What do we do with the waste. Yes.

Senator VOINOVICH. Why don't you bring—why don't you summarize it where we're at real quickly.

Senator CARPER. Crystalize it for me. There's a good word. Crystalize it for me—not the waste, but your answer.

Mr. COLVIN. Crystalize. Yes, sir. Just quickly, we are—the United States made the decision to use a once-through fuel process and ultimately put the waste byproducts, the spent fuel, used fuel from the nuclear power plants in a deep geologic repository, went through a number of citing processes, evaluated that, ultimately chose to evaluate the single site that's at Yucca Mountain, Nevada. That has been being characterized with a lot of science and engineering, and, as I talked about all the "ologies"—hydrology, meteorology, geology, and so on—and evaluated, and that is now waiting to a suitability decision—recommendation, I should say, by the Secretary of Energy to the President some time probably in the latter part of this year.

That will then trigger some policy and procedural issues as regards to the rights of the State of Nevada, and ultimately that issue will likely come back to both the House and the Senate for a simple majority vote to either sustain the veto of Nevada or override that veto and go forward with Yucca Mountain.

If you put that program in place and we move to that point, though, it will likely be an additional 8 to 15 years before that repository goes into full operation and starts actually moving fuel to be emplaced in that repository. It will likely operate for between 100 and 300 years before the decision is ultimately made to close that mountain up and leave it for generations of the future.

Senator CARPER. Anybody else? Anybody on recycling? In terms of new technologies, my understanding of Yucca Mountain is basically we store it there until we fill it up, and then we stop storing it there, or we would.

Mr. COLVIN. Well, ultimately, whether we use—whether we recycle a fuel or whether we use a once-through fuel cycle, ultimately, whatever waste is left over you have to put in some deep geologic repository, and that's the program that each country is looking at, whether it's France or Japan or the United States. The question is whether you do a once-through process or do you recycle it.

President Carter, in 1978, through a policy decision, our Government made the decision we would not recycle, and we're going down that path. Today to change that would be hugely costly without a lot of gain—were the Nation accepting, perhaps the size of what ultimately goes into Yucca Mountain or whatever repository.

But, just to give you a size consideration, all the fuel from all our Nation's 103 plants operating after 40 years would fill a football field 10 yards deep. We're not talking about a huge volume of waste, as compared to other types of waste products or byproducts that we have to dispose of.

Senator CARPER. Say that again?

Mr. COLVIN. It's about one football field 10 yards deep would take all the waste from the Nation's 103 nuclear power plants operating over 40 years.

Senator CARPER. All right. Thank you.

Anybody else?

[No response.]

Senator CARPER. Mr. Chairman, thank you very much.

Senator VOINOVICH. Thank you.

We thank the panel for your patience, and apologize for the long delay. It's very embarrassing to me, but that's the way the Senate operates.

Mr. COLVIN. It's not your fault.

Senator VOINOVICH. Yes, but I just want all of you to know how grateful I am for your patience and your being here today. Some of you have come from out of State to be here. Thank you so much for being here. We appreciate it.

[Whereupon, at 12:43 p.m., the subcommittee was adjourned, to reconvene at the call of the chair.]

[Additional statements submitted for the record follows:]

STATEMENT OF HON. RICHARD A. MESERVE, CHAIRMAN, NUCLEAR REGULATORY COMMISSION

INTRODUCTION

Mr. Chairman, members of the Subcommittee, it is a pleasure to appear before you today with my fellow Commissioners. I would like to take this opportunity to acknowledge the strong support this Subcommittee provided in the 106th Congress in enacting legislation which addresses the long-standing fairness in funding issue. We also appreciate the Subcommittee's and full Committee's efforts in support of the Nuclear Regulatory Commission's (NRC's) other legislative proposals in the 106th Congress, most of which were included in S. 1627 which passed the Senate. We look forward to working constructively with you in the new Congress.

As you know, the NRC's mission is to ensure the adequate protection of public health and safety, the common defense and security, and the environment in the application of nuclear technology for civilian use. The Commission does not have a promotional role—rather, the agency seeks to ensure the safe application of nuclear technology if society elects to pursue the nuclear energy option.

The Commission recognizes, however, that its regulatory system should not establish inappropriate impediments to the application of nuclear technology. Many of the Commission's initiatives over the past several years have sought to maintain or enhance safety while simultaneously improving the efficiency and effectiveness of our regulatory system. We believe the Commission's most recent legislative proposals would enhance safety and improve our regulatory system even further and are pleased to see that many of our proposals have been incorporated into the bills before this Congress. The Commission also recognizes that its decisions and actions as a regulator influence the public's perception of the NRC and ultimately the public's perception of the safety of nuclear technology. For this reason, the Commission's primary performance goals also include increasing public confidence.

BACKGROUND

Currently there are 104 nuclear power plants licensed by the Commission to operate in the United States in 31 different States. As a group, they are operating at high levels of safety and reliability. (See Charts on Attachments 1 and 2.)

These plants have produced approximately 20 percent of our nation's electricity for the past several years and are operated by about 40 different companies. In 2000, these nuclear power plants produced a record 755 thousand gigawatt-hours of electricity. (See Graph on Attachment 3.)

Improved Licensee Efficiencies (Increased Capacity Factors)

The Nation's nuclear electricity generators have worked over the past 10 years to improve nuclear power plant performance, reliability, and efficiency. According to

the Nuclear Energy Institute, the improved performance of the U.S. nuclear power plants since 1990 is equivalent to placing 23 new 1000 MWe power plants on line. The average capacity factor for U.S. light water reactors was 88 percent in 2000, up from 63 percent in 1989.[1] (See Table on Attachment 3.) The Commission has focused on ensuring that safety is not compromised as a result of these industry efforts. The Commission seeks to carry out its regulatory responsibilities in an effective and efficient manner so as not to impede industry initiatives inappropriately.

Electric Industry Restructuring

As you are aware, the nuclear industry is undergoing a period of remarkable change. The industry is in a period of transition in several dimensions, probably experiencing more rapid change than in any other period in the history of civilian nuclear power. As deregulation of electricity generation proceeds, the Commission is seeing significant restructuring among the licensees and the start of the consolidation of nuclear generating capacity among a smaller group of operating companies. This change is due, in part, to an industry that has achieved gains in both economic and safety performance over the past decade and thus is able to take advantage of the opportunities presented by industry restructuring.

INITIATIVES IN THE AREA OF CURRENT REACTOR AND MATERIALS REGULATION

License Transfers

One of the more immediate results of the economic deregulation of the electric power industry has been the development of a market for nuclear power plants as capital assets. As a result, the Commission has seen a significant increase in the number of requests for approval of license transfers. These requests have increased from a historical average of about two or three per year, to 20–25 in the past 2 years.

The Commission seeks to ensure that our reviews of license transfer applications, which focus on adequate protection of public health and safety, are conducted efficiently. These reviews sometimes require a significant expenditure of staff resources to ensure a high quality and timely result. Our legislative proposal to eliminate foreign ownership review could help to further streamline the process. To date, the Commission believes that it has been timely in these transfers. For example, in CY 2000, the staff reviewed and approved transfers in periods ranging from four to 8 months, depending on the complexity of the applications. The Commission will strive to continue to perform at this level of proficiency even in the face of continued demand.

License Renewals

Another result of the new economic conditions is an increasing interest in license renewal that would allow plants to operate beyond the original 40-year term. That maximum original operating term, which for many plants were established in the Atomic Energy Act (AEA), did not reflect a limitation that was determined by engineering or scientific considerations, but rather was based on financial and antitrust concerns. The Commission now has the technical bases and experience on which to make judgments about the potential useful life and safe operation of facilities and is addressing the question of extensions beyond the original 40-year term.

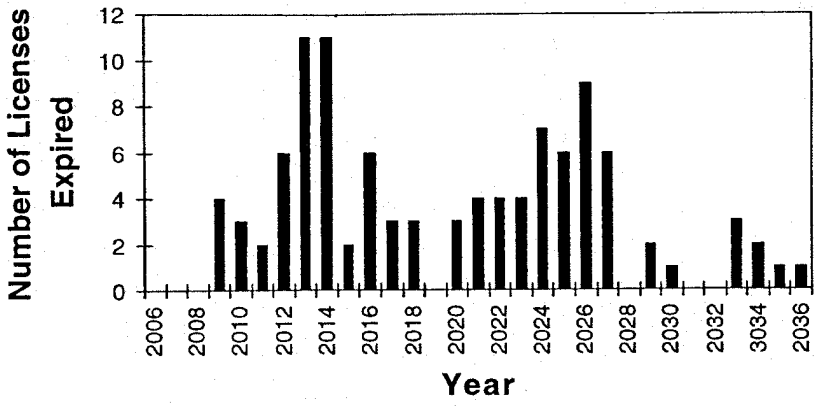
The focus of the Commission's review of applications is on maintaining plant safety, with the primary concern directed at the effects of aging on important systems, structures, and components. Applicants must demonstrate that they have identified and can manage the effects of aging so as to maintain an acceptable level of safety during the period of extended operation.

The Commission has now renewed the licenses of plants at two sites for an additional 20 years: Calvert Cliffs in Maryland, and Oconee in South Carolina, comprising a total of five units. The thorough reviews of these applications were completed ahead of schedule, which is indicative of the care exercised by licensees in the preparation of the applications and the planning and dedication of the Commission staff. Applications for units from three additional sites—Hatch in Georgia, ANO–1 in Arkansas, and Turkey Point in Florida—are currently under review. As indicated by our licensees, many more applications for renewal are anticipated in the coming years.

Although the Commission has met or exceeded the projected schedules for the first reviews, it would like the renewal process to become as effective and efficient as possible. The extent to which the Commission is able to sustain or improve on

[1] Capacity factor is the ratio of electricity generated, for the period of time considered, to the amount of energy that could have been generated at continuous full-power operation during the same period.

our performance depends on the rate at which applications are actually received, the quality of the applications, and the staff resources available to complete the review effort. The Commission recognizes the importance of license renewal and is committed to providing high-priority attention to this effort. As you know, the Commission encourages early notification by licensees of their intent to submit license renewal applications in order to allow adequate planning of demands on staff resources. The Commission is committed to maintaining the quality of its safety reviews.



Reactor Plant Power Uprates

In recent years, the Commission has approved numerous license amendments that permit licensees to make relatively small power increases or uprates. Typically, these increases have been approximately 2 percent to 7 percent. These uprates, in the aggregate, resulted in adding approximately 2000 MWe or two new 1000 MWe power plants.

The NRC is now reviewing five license amendment requests for larger power uprates. These requests are for Boiling Water Reactors (BWR's) and are for uprates of 15 percent to 20 percent. (There are two primary designs for operating light water reactors: Boiling Water Reactors and Pressurized Water Reactors.) While the staff has not received requests for additional uprates beyond these five, some estimates indicate that as many as 22 BWR'S may request uprates in the 15 percent to 20 percent range. These uprates, if allowed, could add approximately 3,000 to 4,500 MWe to the grid.

Approvals for uprates are granted only after a thorough evaluation by NRC staff to ensure safe operation of the plants at the higher power. Plant changes and modifications are necessary to support a large power uprate, and thus require significant financial investment by the licensee. While the NRC does not know the number of uprate requests that will be received, the staff is evaluating ways to streamline the review and approval process. As with license renewals, the Commission encourages early notification by licensees, in advance of their applications for uprates, in order to allow adequate planning of demands on staff resources.

Nuclear Materials Program

I also want to highlight our nuclear materials program for you. We have a very large number of materials-related initiatives underway. As with our reactor program, we are working on making our nuclear materials regulation more risk-informed and flexible. For example, we are in the final steps of totally revising our regulations governing the medical use of byproduct material using risk insights, together with other factors, to establish requirements that better focus licensee and regulatory attention on issues commensurate with their importance to health and safety. We are also revising our regulations governing the licensing of fuel cycle facilities to introduce the use of an integrated safety assessment, thereby incorporating risk insights into the regulation of these facilities. We are also working with the international community to learn about problems associated with facilities and materials programs abroad, most recently illustrated by events in Japan and Thailand.

We are currently reviewing the Construction Application Request for a mixed-oxide fuel fabrication facility at the Department of Energy's (DOE's) Savannah

River site in South Carolina. In coordination with that effort, we also are conducting scoping meetings with stakeholders for the development of the Environmental Impact Statement to support NRC's licensing reviews of a MOX facility.

We continue to decommission various complex materials sites around the country. We are working to finalize our policy statement on the cleanup criteria to be applied at DOE's West Valley site in New York and we continue to provide technical assistance to DOE on related technical matters, including cleanup of the high-level waste tanks at the Savannah River site.

We are also revising our requirements for the transportation of spent fuel and radioactive material to make them more risk-informed and consistent with international standards. We are doing this in partnership with the Department of Transportation, which will simultaneously revise its own rule in this area. Finally, we are working to address the complex issues associated with regulating the uranium recovery industry at a time when uranium prices remain at historic lows. Let me now move on to the storage and disposal of high-level waste and spent fuel.

High-Level Waste Storage/Disposal (Spent Fuel Storage)

In the past several years, the Commission has responded to numerous requests to approve spent fuel cask designs and independent spent fuel storage installations for onsite dry storage of spent fuel. These actions have provided an interim approach pending implementation of a program for the long-term disposition of spent fuel. The ability of the Commission to review and approve these requests has provided the needed additional onsite storage of spent nuclear fuel, thereby avoiding plant shutdowns as spent fuel pools reach their capacity. The Commission anticipates that the current lack of a final disposal site will result in a large increase in onsite dry storage capacity during this decade.

The Commission is currently reviewing an application for an Independent Spent Fuel Storage Installation on the reservation of the Skull Valley Band of Goshute Indians in Utah.

Certain matters also need to be resolved in order to make progress on a deep geologic repository for disposal of spent nuclear fuel. The Energy Policy Act of 1992 requires the Environmental Protection Agency (EPA) to promulgate general standards to govern the site, while the Commission has the obligation to implement those standards through its licensing and regulatory process. The Commission has concerns about certain aspects of EPA's proposed approach and is working with EPA to resolve these issues. Some of our legislative proposals would eliminate these issues.

We continue to prepare for a potential license application from DOE for the proposed high-level waste geologic repository at Yucca Mountain. These efforts include periodic technical exchange meetings between NRC and DOE staff which are open to the public.

Risk—Informing the Commission's Regulatory Framework

The Commission also is in a period of dynamic change as the agency moves from a prescriptive, deterministic approach toward a more risk-informed and performance-based regulatory paradigm. Improved probabilistic risk assessment techniques combined with more than four decades of accumulated experience with operating nuclear power reactors has led the Commission to recognize that some regulations may not serve their intended safety purpose and may not be necessary to provide adequate protection of public health and safety. Where that is the case, the Commission has determined it should revise or eliminate the requirements. On the other hand, the Commission is prepared to strengthen our regulatory system where risk considerations reveal the need.

Perhaps the most visible aspect of the Commission's efforts to risk-inform its regulatory framework is the new reactor oversight process. The process was initiated on a pilot basis in 1999 and fully implemented in April 2000. The new process was developed to focus inspection effort on those areas involving greater risk to the plant and thus to workers and the public, while simultaneously providing a more objective and transparent process. Although the Commission continues to work with its stakeholders to assess the effectiveness of the revised oversight process, the feedback received from industry and the public is favorable.

FUTURE ACTIVITIES

Scheduling and Organizational Assumptions Associated with New Reactor Designs

While improved performance of operating nuclear power plants has resulted in significant increases in electrical output, significant increased demands for electricity will need to be addressed by construction of new generating capacity of some type. Serious industry interest in new construction of nuclear power plants in the

United States has only recently emerged. As you know, the Commission has already certified three new reactor designs pursuant to 10 CFR Part 52. These designs include General Electric's advanced boiling water reactor, Westinghouse's AP–600 and Combustion Engineering's System 80+. Because the Commission has certified these designs, a new plant order may include one of these approved designs. However, the staff is also conducting a preliminary review associated with other new designs. Licensees have also indicated to the NRC that applications for early site permits could be submitted in the near future. These permits would allow pre-certification of sites for possible construction of nuclear power plants.

In addition to the three already certified advanced reactor designs, there are new nuclear power plant technologies, such as the Pebble Bed Modular Reactor, which some believe can provide enhanced safety, improved efficiency, and lower costs, as well as other benefits. To ensure that the Commission staff is prepared to evaluate any applications to introduce these advanced nuclear reactors, the Commission recently directed the staff to assess the technical, licensing, and inspection capabilities that would be necessary to review an application for an early site permit, a license application, or construction permit for a new reactor unit. This will include the capability to review the designs for Generation III+ or Generation IV light water reactors, including the Westinghouse AP–1000, the Pebble Bed Modular Reactor, General Atomics' Gas Turbine Modular Helium Reactor, and the International Reactor Innovative and Secure (IRIS) designs. In addition to assessing its capability to review the new designs, the Commission will also examine its regulations relating to license applications, such as 10 CFR Parts 50 and 52, in order to identify whether any enhancements are necessary. We also recently established the Future Licensing Project Organization in order to prepare for and manage future reactor and site licensing applications.

In order to confirm the safety of new reactor designs and technology, the Commission believes that a strong nuclear research program should be maintained. A comprehensive evaluation of the Commission's research program is underway with assistance from a group of outside experts and from the Advisory Committee on Reactor Safeguards. With the benefit of these insights, the Commission expects to undertake measures to strengthen our research program over the coming months.

Human Capital

Linked to these technical and regulatory assessments, the Commission is reviewing its human capital to ensure that the appropriate professional staff is available for the Commission to fulfill its traditional safety mission, as well as any new regulatory responsibilities in the area of licensing new reactor designs.

In some mission critical offices within the Commission, nearly 25 percent of the staff are eligible to retire today. In fact, the Commission has six times as many staff over the age of 60 as it has staff under 30.

And, as with many Federal agencies, it is becoming increasingly difficult for the Commission to hire personnel with the knowledge, skills, and abilities to conduct the safety reviews, licensing, research, and oversight actions that are essential to our safety mission. Moreover, the number of individuals with the technical skills critical to the achievement of the Commission's safety mission is rapidly declining in the Nation, and the educational system is not replacing them. The Commission's staff has taken initial steps to address this situation, and as a result, is now seeking systematically to identify future staffing needs and to develop strategies to address the gaps. It is apparent, however, that the maintenance of a technically competent staff will require substantial effort for an extended time. The various Senate energy bills properly give attention to such matters. The Commission would be pleased to offer some further suggestions in the same vein.

Budget

The NRC is proposing a fiscal year 2002 budget of $513.1 million. This represents approximately a 5.3 percent ($25.8 million) increase over the fiscal year 2001 budget. Our budget proposal will allow the NRC to continue adequately to protect the public health and safety, promote the common defense and security, and protect the environment, while providing sufficient resources to address increasing personnel costs and increasing workloads. Approximately 60 percent of the budget growth is for increasing personnel costs, primarily the pay raise that the President has authorized for Federal employees. The remaining increase is required for several purposes: to continue preparing for the review of a potential Department of Energy application to build a high-level radioactive waste geologic repository; to review four additional reactor license renewal applications; to develop environmental assessments for decommissioning or terminated license requests; to sustain important reactor and waste safety research; and to pay for increased operating costs associated

with rent and transit subsidies. At the same time, the number of employees at the agency continues to reflect almost a 20 percent reduction in staff since fiscal year 1993. Two charts reflecting a summary of our budget since fiscal year 1993 are Attachments 4 and 5 to this testimony.

The NRC recently submitted a proposed bill for authorization of appropriations for fiscal year 2002. We respectfully request the Committee's support for our budget request. However, as I mentioned earlier, serious industry interest in new construction of nuclear power plants has only recently emerged. Therefore, our budget proposal does not include resources to prepare for this initiative.

LEGISLATIVE PROPOSALS

The Commission has identified in its legislative proposals areas where new legislation would be helpful to eliminate artificial restrictions and to reduce the uncertainty in the licensing process. These changes would maintain safety while increasing flexibility in decisionmaking. Although those changes would have little or no immediate impact on electrical supply, they would help establish the context for consideration of nuclear power by the private sector without any compromise of public health and safety or protection of the environment.

Legislation will be needed to extend the Price-Anderson Act. The Act, which expires on August 1, 2002, establishes a framework that provides assurance that adequate funds are available in the event of a nuclear accident and sets out the process for consideration of nuclear claims. Without the framework provided by the Act, private-sector participation in nuclear power would be discouraged by the risk of large liabilities.

Reorganization Plan No. 3 of 1970 could be revised to provide the Commission with the sole responsibility to establish all generally applicable standards related to Atomic Energy Act (AEA) materials, thereby avoiding dual regulation of such matters by other agencies. Along these same lines, the Nuclear Waste Policy Act of 1982 could be amended to provide the Commission with the sole authority to establish standards for high-level radioactive waste disposal. These changes would serve to provide full protection of public health and safety, provide consistency, and avoid needless and duplicative regulatory burden.

Commission antitrust reviews of new reactor licenses could also be eliminated. As a result of the growth of Federal antitrust law since the passage of the AEA, the Commission's antitrust reviews are redundant of the reviews of other agencies. The requirement for Commission review of such matters, which are distant from the Commission's central expertise, should be eliminated.

Elimination of the ban on foreign ownership of U.S. nuclear plants would be an enhancement since many of the entities that are involved in electrical generation have foreign participants, thereby making the ban on foreign ownership increasingly problematic. The Commission has authority to deny a license that would be inimical to the common defense and security, and thus an outright ban on all foreign ownership is unnecessary.

With the strong congressional interest in examining energy policy, the Commission is optimistic that there will be a legislative vehicle for making these changes and thereby for updating the AEA. Indeed, we note that certain of these matters are included in bills now before this Committee.

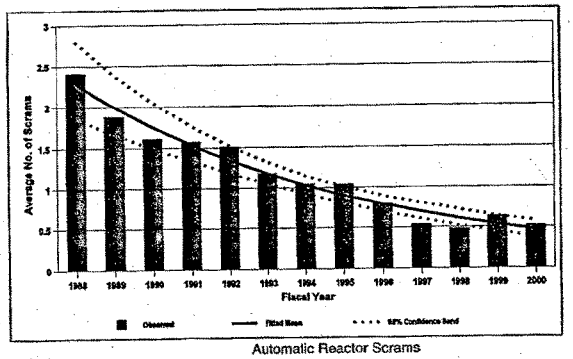
SUMMARY

The Commission has long been, and will continue to be, active in concentrating its staffs' efforts on ensuring the adequate protection of public health and safety, the common defense and security, and the environment in the application of nuclear technology for civilian use. Those statutory mandates notwithstanding, the Commission is mindful of the need: (1) to reduce unnecessary burdens, so as not to inappropriately inhibit any renewed interest in nuclear power; (2) to maintain open communications with all of its stakeholders, in order to seek to ensure the full, fair, and timely consideration of issues that are brought to our attention; and (3) to continue to encourage its highly qualified staff to strive for increased efficiency and effectiveness, both internally and in our dealings with all of the Commission's stakeholders.

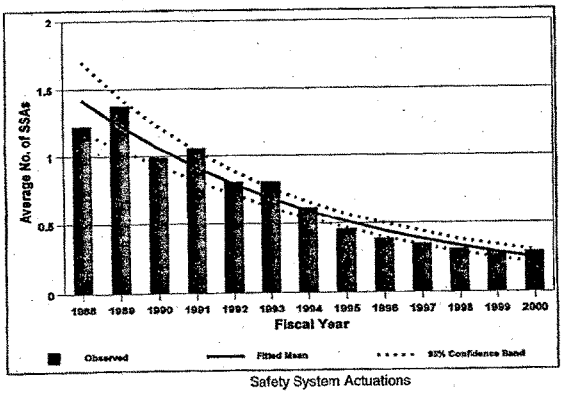
Thank you Mr. Chairman, I welcome your comments and questions.

Attachment 1

NRC Performance Indicators; Annual Industry Averages, 1988-2000

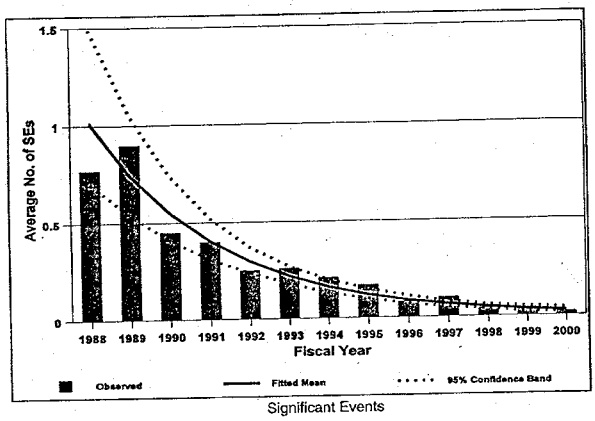


Automatic Reactor Scrams

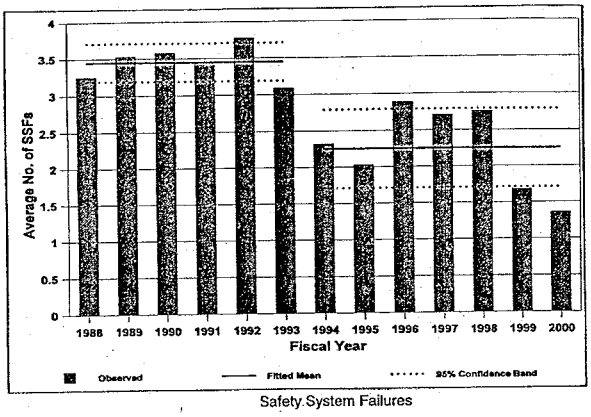


Safety System Actuations

Attachment 2

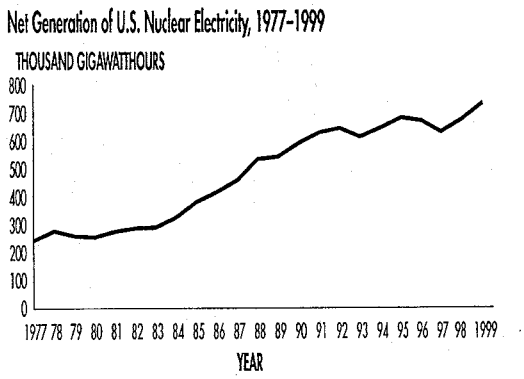


Significant Events



Safety System Failures

Attachment 3

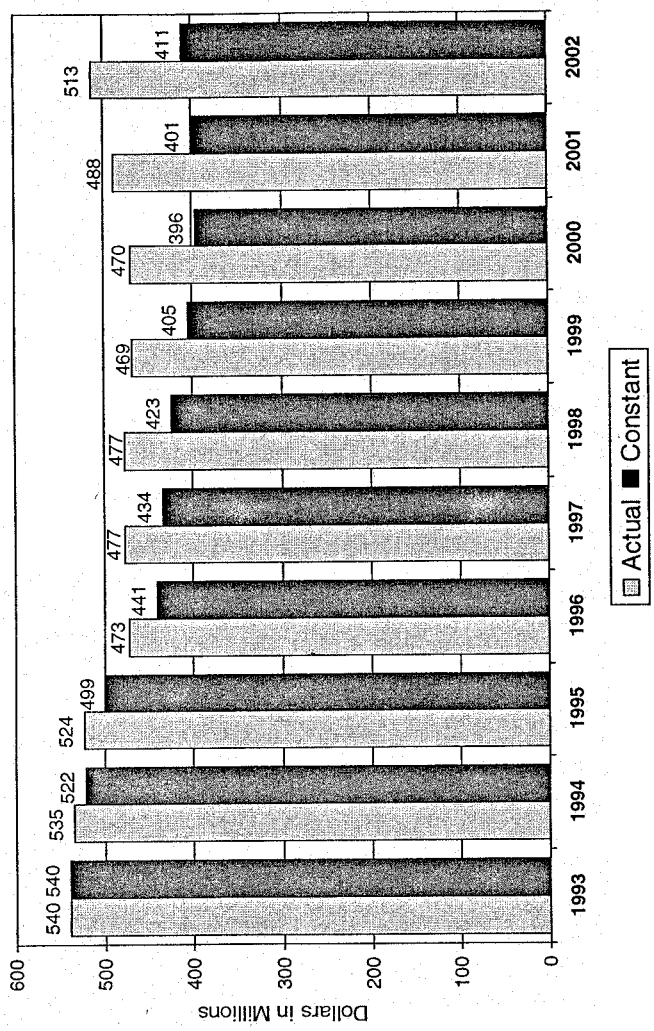


U.S. Commercial Nuclear Power Reactor Average Capacity Factor

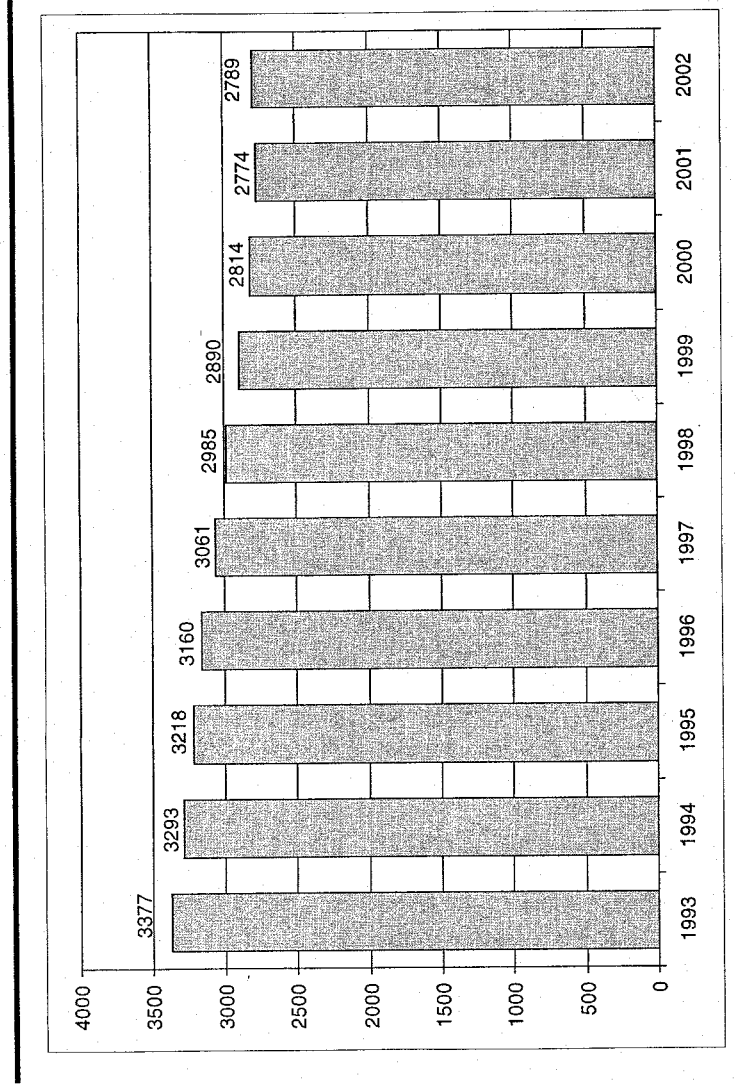
Year	Number of Reactors Licensed to Operate	Average Annual Capacity Factor	Percent of Total U.S.
1989	109	63	19.0
1990	111	68	20.5
1991	111	71	21.7
1992	110	71	22.2
1993	109	73	21.2
1994	109	75	22.1
1995	109	79	22.5
1996	110	77	21.9
1997	104	74	20.1
1998	104	78	22.6
1999	104	86	22.9
2000	104	88	23.4

Attachment 4

FY 1993 – 2002 BUDGET SUMMARY



Attachment 5



RESPONSES BY RICHARD MESERVE TO ADDITIONAL QUESTIONS FROM SENATOR REID

Question 1. How many currently licensed nuclear power plants have foreign ownership?

Response. Three power reactors, Three Mile Island, Unit 1, Clinton, and Oyster Creek, are owned by AmerGen. British Energy, Inc., a foreign company, indirectly owns 50 percent of AmerGen, and thus is an indirect owner of these plants. In addition, New England Power owns about 10 percent of the Seabrook plant and about 12 percent of Millstone, Unit 3. New England Power is an indirect wholly-owned subsidiary of the National Grid Group, a British company. However, Millstone 3, including New England Power's share, is being sold to a U.S. company and Seabrook is also beginning the sale process.

In a few instances, a small percentage of stock in U.S. companies that own nuclear power plants may be held by foreign individuals or entities. In order to ensure, in part, that power reactor licensees inform the NRC of such situations, the NRC issued Regulatory Issue Summary (RIS) 2000–01 on February 1, 2000. This RIS reminded power reactor licensees of their obligation to inform the NRC when changes occur with respect to foreign ownership, control, or domination in ways that include, but are not limited to the following: (1) a license holder becomes aware of changes in foreign ownership or control of its company or of its parent company, for example, by receiving Securities and Exchange Commission Schedules 13D or 13G indicating such changes; (2) a license holder, or its parent company, plans to merge with or be acquired by an entity that is owned, controlled, or dominated by foreign interests; or (3) a license holder's Board of Directors becomes controlled or dominated by board members who are not U.S. citizens.

Question 2. How many of the principal nuclear power engineering, maintenance, and equipment supply companies have significant foreign investment?

Response. This question goes to the heart of why we believe that the foreign ownership prohibitions on utilization facilities (i.e., commercial and research reactors) in Sections 103d and 104d of the Atomic Energy Act should be eliminated. The current prohibitions apply only to utilization and production facilities, not to the enterprises listed in the question. (A separate foreign ownership prohibition in Section 193(f) applies to the United States Enrichment Corporation. The Commission is not proposing to eliminate that prohibition or the prohibition on production facilities in Sections 103d and 104d.)

Many enterprises—arguably more sensitive than nuclear reactors from a common defense and security prospective—have long had significant foreign ownership, primarily from Europe and Japan. The vendors of three of the four reactor designs currently deployed in our 104 licensed reactors—Westinghouse, Combustion Engineering, and Babcock and Wilcox—are foreign-owned. Only General Electric is American-owned. The vendor of two of the three currently NRC certified advanced reactor designs is foreign. The Pebble Bed Modular Reactor design team is South African-based, with a U.S. firm—Exelon—having a minority interest. Other advanced reactor designs are likely to be international as well.

Similarly, six of the seven major fuel cycle facilities currently licensed by NRC have significant or total foreign ownership. Only Nuclear Fuel Services, Inc., one of the two category 1 fuel cycle facilities which handles highly enriched uranium (HEU), is entirely U.S. owned by a U.S. corporation. The other category 1 fuel cycle facility—BWX Technologies, Inc.—is owned by McDermott International, Inc., a Panama corporation which is a publicly traded company on the New York Stock Exchange. In that case, consistent with the statutory requirement to ensure common defense and security, the Commission in consultation with the Department of Energy (DOE) required a variety of mitigating measures, such as an oversight board comprised wholly of U.S. members. The only new fuel cycle facility currently planned, the mixed oxide fuel facility to be built at the DOE Savannah River, South Carolina site to carry out the DOE weapons plutonium disposition mission, will also have significant foreign involvement.

The Commission believes that the common defense and security provisions in Sections 103d and 104d of the Atomic Energy Act are sufficient to ensure that any foreign ownership of a U.S. utilization facility will not be inimical to U.S. security, just as similar provisions elsewhere in the Atomic Energy Act have ensured that other arguably more sensitive facilities and enterprises do not have unacceptable foreign owners. The foreign ownership restrictions on nuclear power plants are out of date because the nuclear industry, like most high technology industries, has for some time been an international enterprise. The categories of reactor vendors, construction firms, fuel cycle facilities, spent fuel cask manufacturers, and reactor component manufacturers all have significant foreign ownership. Commercial nuclear power plants should, in our view, be treated similarly.

Question 3. The Administration has indicated a concern with our dependence on foreign energy supplies. Do you think we should allow significant control over our nuclear power supply?

Response. We understand that the Administration's concerns with dependence on foreign energy supply relates primarily to fuels, such as petroleum, that are imported from foreign nations, and that might present an economic or national-security threat if interrupted. As noted in response to the previous question, the Commission is not proposing to eliminate either the foreign ownership restriction for production facilities (enrichment or reprocessing facilities) or the separate foreign ownership prohibition in Section 193(f) that applies to the United States Enrichment Corporation. The Commission believes that these foreign ownership restrictions on more sensitive facilities still serve the purpose that motivated their adoption.

The Commission submitted proposed legislation to Congress that would amend Sections 103d and 104d of the Atomic Energy Act of 1954, as amended (AEA), by removing the prohibition against foreign ownership, control, or domination of utilization facilities (which include both power and research and test reactors). It is the Commission's understanding that Congress has not restricted foreign ownership of other sources of domestic energy supply. A *per se* prohibition against foreign ownership of utilization facilities, which originated in the 1954 enactment of the AEA at a time when commercial development of nuclear power was in its incipient stages, is outdated and unnecessary. The Commission believes that significant foreign ownership within the U.S. nuclear power industry could be allowed without adversely affecting common defense and security. The general non-inimicality restriction contained in Sections 103d and 104d provides ample authority for the Commission to refuse to issue a license or take other actions in cases where foreign ownership would be inconsistent with the national defense and security or other policies of the United States.

Question 4. Did the NRC conduct an analysis of the subsidy the Price-Anderson Act provides the nuclear industry? If so, what did the NRC determine the subsidy to be?

Response. The NRC has not analyzed "the subsidy issue" since its December 1983 Report to Congress. See the Price-Anderson Act—The Third Decade (NUREG-0957). As a result of the 1988 Price-Anderson Act Amendments, the observation "a subsidy may exist" had become obsolete or at the least a tenuous conclusion. To date, no Federal government funds have been paid out as a result of damage claims under Price-Anderson Act against licensed nuclear facilities.

Before the 1988 modifications to the Act and pursuant to the 1975 Price-Anderson amendments, enacted as P.L. 94-197, each licensee of a power reactor with a capacity of 100,000 kilowatts electric or more was required to contribute to a retrospective premium pool. The contribution, then a one time contribution of $5 million, was called for only in the event that public liability as a result of an accident exceeded the commercial insurance coverage. That first layer of protection was, and remains, by statutory requirement, the maximum commercial insurance available at a reasonable price. Originally, government indemnification came into play immediately after the insurance layer was exhausted. The government commitment was to be sufficient to achieve a total of $560 million per reactor per accident, which was also the limit of liability. At that time $60 million was available as insurance. The 1975 amendments introduced the industry retrospective premium pool which delayed the time and lessened the amount of government exposure. In 1982, as a result of additional reactors added to the pool, government exposure was eliminated entirely, unless by some unexpected event the size of the pool were to diminish so that some government contribution would again be possible.

The 1988 amendments significantly increased the size of the retrospective premium owed by each reactor licensee to $63 million to be adjusted regularly for inflation. This premium is now, as adjusted, $83.9 million. This brings the available funds in the event of an accident to over $9 billion, effectively eliminating any reasonable likelihood of dropping below the $560 million mark at which the Federal government would become exposed. Thus, under current law the totality of funds for compensation of public liability up to the allowable limit is payable by direct insurance of the facility owner or the retrospective premium pool. This supports the conclusion that there is no direct subsidy in the Price-Anderson scheme.

The Price-Anderson Act contains a Congressional commitment to provide the means for prompt and full compensation if the sum of liabilities exceeds the limit on liability and the available funds, now over $9 billion. However, the statutory language notes expressly that the limitation of liability provision may not be construed to preclude the Congress from raising the funds by enacting a revenue measure ap-

plicable to NRC licensees maintaining financial protection under Section 170b (i.e., the commercial nuclear power reactors).

We believe that the 1988 Amendments also extinguished or lessened any cause to consider the limitation on liability to be a subsidy. To be a subsidy, the grant or other form of encouragement must be one-way, i.e., without equivalent compensation. Such is not the case here. Even when the liability limit was only $560 million, the United States Supreme Court found that Price-Anderson "does, in our view, provide a reasonable just substitute for the common-law or State tort law remedies it replaces." *Duke Power Co.* v. *Carolina Env. Study Group*, 438 U.S. 59,88 (1978). The Court found that benefits to the public provided a *quid pro quo* for the liability limit and firmly rejected the argument that "no *quid pro quo* can be provided by the Act since without it there would be no nuclear power plants and no possibility of accidents or injuries." Id at n. 33 and related text.

Today the Act serves the public by ensuring the availability of over $9 billion to cover injuries sustained to person or property. Moreover, the licensees must waive various defenses and the industry insurance and premium pool must pay out no matter who or what caused the accident. These provisions may give greater assurance of compensation than exists under other compensation schemes. The public gains these advantages without cost to the government.

Question 5a. In 1999, the NRC implemented a 1985 rule to limit the types of meetings that would be held in accordance with the Sunshine Act. How many meetings has the NRC held since this new rule went into effect that would have been subject to the Sunshine Act's requirements, but are no longer?

Response. The NRC has held four Non-Sunshine Act Discussions since the 1985 rule was implemented in 1999.

Question 5b. What was the nature of these meetings? Who participated? What topics were discussed?

Response. *September 15, 1999; 3:02 p.m.*

Topic discussed: Information briefing on hurricane (Floyd) preparedness activities.

Commissioners present: Chairman Dicus, Commissioner Diaz, Commissioner McGaffigan, and Commissioner Merrifield.

Staff present: Beall, J., Assistant to Commissioner McGaffigan; Castleman, P., Assistant to Commissioner Diaz; Chan, T., Assistant to Chairman Dicus; Congel, F., Incident Response Operations Office; Cyr, K., General Counsel; Dyer, J., Region III; Hart, K., Office of the Secretary; Hasselberg, R., Incident Response Operations Office; Hiltz, T., Assistant to Chairman Dicus; Jones, B., Assistant to r Chairman Dicus; McCabe, B., Assistant to Commissioner Merrifield; Rathbun, D., Office of Congressional Affairs; Shea, J., Assistant to Commissioner Merrifield; Smith, G., Office of the Executive Director for Operations; Thoma, J., Assistant to Commissioner Merrifield; Vietti-Cook, A., Office of the Secretary; and Wert, L., Office of the Executive Director for Operations.

September 22, 1999, 1:05 p.m.

Topic discussed: Media Streaming

Commissioners present: Commissioner Diaz, Commissioner McGaffigan, and Commissioner Merrifield

Staff present: Cloud, J., Office of the Chief Information Officer; Crockett, S., Assistant to Commissioner McGaffigan; Cyr, K., General Counsel; Davis, R., Assistant to Commissioner Diaz; Funches, J., Chief Financial Officer; Goldberg, F., Office of the Chief Information Officer; Greene, K., Office of the Executive Director for Operations; Hart, K., Office of the Secretary; Kirk, I., Office of the Chief Information Officer; Marcy, C., Office of the Chief Information Officer; Marcy, C., Office of Administration; Miraglia, F., Deputy Executive Director for Reactor Programs; Pulliam, T., Office of the Chief Financial Officer; Reiter, S., Acting Chief Information Officer; Schaeffer, J., Office of the Chief Information Officer; Scheffler, T., Office of the Chief Information Officer; Springer, M., Office of Administration; Travers, W., Executive Director for Operations; Vietti-Cook, A., Secretary of the Commission; Wilson, V., Office of Administration

February 18, 2000, 2:00 p.m.

Topic discussed: Indian Point Unit 2 Steam Generator Tube Leak Event Briefing

Commissioners present: Chairman Meserve, Commissioner Dicus, Commissioner Diaz, Commissioner McGaffigan, and Commissioner Merrifield

Staff present: Beall, J., Assistant to Commissioner McGaffigan; Benner, E., Office of Nuclear Reactor Regulation; Black, S., Office of Nuclear Reactor Regulation; Castleman, P., Assistant to Commissioner Diaz; Chan, T., Assistant to Chairman Meserve, Chandler, L., Office of the General Counsel; Clifford, J., Office of Nuclear Reactor Regulation; Collins, S., Office of Nuclear Reactor Regulation; Crockett, S.,

Assistant to Commissioner McGaffigan; Cyr, K., General Counsel; Gray, J., Office of the General Counsel; Harold, J., Office of Nuclear Reactor Regulation; Hayden, E., Office of Public Affairs; Hill W., Office of the Secretary; Hiltz, T., Assistant to Commissioner Dicus; Levin, A., Assistant to Chairman Meserve; Marsh, L., Office of Nuclear Reactor Regulation; McCabe, B., Assistant to Commissioner Merrifield; Miller, H., Region I (via telehone); Murphy, E., Office of Nuclear Reactor Regulation; Portner, L., Office of Congressional Affairs; Rubin, A., Office of Nuclear Regulatory Research; Shea, J., Office of the Executive Director for Operations; Tracy, G., Assistant to Chairman Meserve; Travers, W., Office of the Executive Director for Operations; Tschiltz, M., Office of the Executive Director for Operations; Vietti-Cook, A., Office of the Secretary; Wessman, R., Office of Nuclear Reactor Regulation

March 1, 2000, 10:30 a.m.

Topic discussed: NRC's Y2K Program Lessons Learned Media Streaming

Commissioners present: Commissioner Diaz, Commissioner McGaffigan, and Commissioner Merrifield

Staff present: Bates, A., Office of the Secretary; Beecher, W., Office of Public Affairs; Breskovic, C., Office of International Programs; Castleman, P., Assistant to Commissioner Diaz; Chan, T., Assistant to Chairman Meserve; Chiramal, M., Office of Nuclear Reactor Regulation; Congel, F., Incident Response Operations Office; Hiltz, T., Assistant to Commissioner Discus; Levin, M., Office of the Chief Information Officer; McCabe, B., Assistant to Commissioner Merrifield; Miraglia, F., Office of the Executive Director for Operations; Paperiello, C., Office of the Executive Director for Operations; Ramsey, J., Office of International Programs; Schaeffer, J., Office of the Chief Information Office; Sharkey, J., Assistant to Commissioner McGaffigan; Voglewede, J., Office of the Chief Information Officer

Question 6a. How many of these meetings have involved issues related to the proposed nuclear waste repository at Yucca Mountain or the proposed radiation standards from the EPA?

Response. None.

Question 6b. Who participated in these discussions and what was the nature of them?

Response. N/A

Question 7. I understand the hearing process for possible licensing activities at Yucca Mountain has retained the formal procedures relating to witness cross-examination and evidence discovery. I am encouraged by this decision. Could you explain, however, the reasons the NRC should move away from a formal process for licensing and relicensing activities.

Response. The Commission is considering greater use of informal adjudicatory procedures in order to: (i) conserve parties' and NRC resources which are expended in hearings, (ii) expedite the conduct of hearings to ensure timely decisionmaking, consistent with the rights of all parties, and (iii) enhance the quality of the NRC's adjudicatory decisions. A proposed rule that would streamline and enhance the NRC's hearing procedures through greater use of informal adjudicatory procedures was published in the Federal Register on April 16, 2001 (66 FR 19610).

The Commission believes that in most instances, the use of formal adjudicatory procedures is not essential to the development of an adequate hearing record. All too frequently their use has resulted in protracted, costly proceedings and unfocused hearing records that form poor bases for adjudicatory decisions. The Commission is not alone in its assessment of the relative value of formal adjudications. Over the decades since the Atomic Energy Act was passed, there has been debate over the value of formal, on-the-record adjudication for the resolution of nuclear licensing issues, and indeed for resolving scientific issues generally. There are now many observers who are skeptical that the use of formal adjudication in NRC licensing cases is the appropriate means to settle a regulatory issue; that the arguments for formal adjudication from the 1950s to the 1970s have diminished validity; and that less formalized proceedings could mean not only greater efficiency, but also better decisions, with more meaningful public participation and greater public acceptance of the result. See, e.g., Improving Regulation of Safety at DOE Nuclear Facilities, Final Report of the Advisory Committee on External Regulation of DOE Nuclear Safety, December 1995, at 39.

The Commission has taken a number of steps in recent years to reassess its processes to identify ways in which it can conduct its regulatory activities more effectively. This assessment has extended across the full range of the NRC's programs, from its oversight and inspection program to evaluate and assess licensee performance, to its internal program management activities. The NRC has always sought to ensure that its review processes and decisionmaking are open, understandable,

and accessible to all interested parties. Recently, steps have been taken to expand the opportunities for stakeholder awareness and involvement in NRC policy and decisionmaking through greater use of public workshops in rulemaking, inviting stakeholder participation in Commission meetings, and more extensive use of public meetings with interested parties on a variety of safety and regulatory matters.

The Commission has had a longstanding concern that the hearing process associated with licensing and enforcement actions taken by the NRC is not as effective as it could be. Beginning with case-by-case actions in 1983, and with a final rule in 1989, the Commission took steps to move away from the trial-type, adversarial format to resolve technical disputes with respect to its materials license applications. A significant portion of the NRC's proceedings in the past ten years has been conducted under these informal procedures. Although the Commission's experience to date indicates that some of the original objectives have been achieved, there have also been some aspects of the informal procedures that have continued to prolong the proceeding without truly enhancing the decisionmaking process. Given the Commission's experience, and given the potential in the next few years for new proceedings to consider applications for new facilities, to renew reactor operating licenses, and to reflect restructuring in the electric utility industry, the Commission concluded that it should identify improvements to its hearing process that will result in a better use of all participants' limited resources.

Accordingly, the Commission believes that a comprehensive restructuring of the Commission's adjudicatory procedures is appropriate. The procedures proposed in the recent Federal Register notice should reduce the burden of litigation costs on applicants and other participants because of the informal, less adversarial nature of the hearing. Less formal procedures will also enhance the role of the presiding officer as a technical fact finder by giving him or her the primary responsibility for controlling the development of the hearing record. This should lead to better adjudicatory decisions. Finally, less formal procedures should result in more timely completion of hearings and issuance of decisions.

RESPONSES BY RICHARD MESERVE TO QUESTIONS FROM SENATOR CLINTON

Question 1. Describe the regulatory activities that are planned or underway, as well as the schedule and resources needed, to continue to refine and improve the recently implemented risk-informed approach to ensuring safe nuclear power plant operation.

Response. Refinement and improvement of the new Reactor Oversight Process (ROP) are ongoing activities. The NRC has implemented a self-assessment program to evaluate the overall success of the ROP in being objective, risk-informed, understandable, and predictable, as well as its success in meeting the agency's performance goals of maintaining safety, protection of the environment and the common defense and security; increasing public confidence; making NRC activities and decisions more effective, efficient, and realistic; and reducing unnecessary regulatory burden. On a periodic basis, the self-assessment program collects information from various sources, including resource utilization and performance databases, inspection program feedback, periodic independent audits, stakeholder feedback, and public comment. This information forms the basis to evaluate ROP effectiveness and additional program improvements.

The most significant initiatives that are currently underway to continue to improve and refine the ROP are discussed below. Most of these activities are expected to be completed within the upcoming year, and can be completed with the resources currently budgeted for the continued development of the ROP. These initiatives are as follows:

- incorporate lessons learned from the first year of full implementation, which ended in April 2001;
- investigate program areas and implement changes where resource efficiencies can be gained;
- refine and streamline the significance determination process;
- enhance inspector training;
- develop additional and more effective performance indicators; and
- investigate areas where inspection procedures and performance assessment can be streamlined.

The results of initial implementation indicate that current regional and program development resource levels were adequate to carry out the first year of the ROP effectively and to achieve its objectives. Future resource reductions may be possible through efficiencies gained as a result of the elimination of startup costs, improve-

ments to documentation methods, and refinements in the significance determination process. In addition, savings may be possible through reductions of plant-specific inspections (i.e., event follow-up and inspections to follow up on significant performance issues) contingent upon continued improvements in plant performance. However, these will need to be weighed against emerging programs and policies that may impact future resources.

In addition to implementing the ROP, the NRC has pursued improvements to our regulations to make them more risk-informed. The two major initiatives currently underway are commonly referred to as "Option 2" and "Option 3". Option 2 refers to our initiative to risk-inform certain requirements in 10 CFR Part 50 that specify quality, testing, inspection, and other "special treatment" requirements to be applied to structures, systems, and components (SSCs) in nuclear power plants. The intent of the Option 2 rulemaking is to provide an alternative set of requirements that would vary the treatment applied to SSCs on the basis of safety significance using a risk-informed categorization method. SSCs that are safety significant would be subject to greater regulatory controls than those of lower significance. The licensee for the South Texas plant has requested exemptions from some of the existing "special treatment" requirements. The staff is evaluating the merits of this request and expects to issue a final safety evaluation in the near future. The South Texas plant application is viewed as a "proof of concept" for the Option 2 approach through which we expect to gain valuable experience.

Option 3 refers to our initiative to identify existing "technical" requirements in our reactor safety regulations that are candidates for risk-informed regulation. One example of the potential changes to the regulations concerns combustible gas control during accidents to make the regulations more risk-informed and performance-based. We are also considering other potential changes, particularly with respect to our requirements concerning emergency core cooling system operations.

Question 2. Explain how this new approach will maintain the same level of safety, predictability, and consistency as the old approach.

Response. The revised Reactor Oversight Process (ROP) was developed to maintain the level of safety of operating nuclear power reactors while improving the predictability and consistency of the previous process. It maintains safety by using inspections and performance indicators to indicate safe operation within seven cornerstones of safety: initiating events, mitigating systems, integrity of barriers to the release of radioactivity, emergency preparedness, occupational radiation safety, public radiation safety, and physical protection from sabotage. Based on the significance of inspection and performance indicator results, the NRC will take timely action to ensure that licensees address performance issues before they result in unacceptable performance.

The ROP has improved predictability in several ways. First, each plant reports a set of performance indicators compared with pre-established thresholds each calendar quarter. Second, inspection findings are evaluated for their significance to safety using the significance determination process. This objective, documented process clearly communicates results, along with the underlying assumptions, such that all stakeholders understand the significance of inspection findings. And third, the process for assessing plant performance combines the results of objective indicators and inspection findings and uses a published "action matrix" to determine the actions the agency will take to follow up performance problems and ensure they are appropriately addressed. These aspects of the ROP make the NRC's assessment process a more objective and predictable one.

The ROP has also improved consistency by: (1) more clearly defining the base level of inspection, (2) relying on an objective process for evaluating the significance of inspection findings and determining follow up actions, and (3) relating enforcement actions to the objective evaluation of findings and assessment of overall performance. Also, the revised Reactor Oversight Process changed how the agency documents its reactor inspections, primarily documenting the facts used by inspectors to objectively evaluate the significance of the findings, and eliminating subjective observations and conclusions.

The inspections under the ROP are more risk-informed; that is they focus the NRC and licensees on areas of greater risk significance, and place less focus on areas of lesser safety significance. More information about each plant's safety performance is available to the general public more frequently.

Question 3. Provide information on the performance indicators selected for use in the new risk-informed approach, and how these indicators will track all inspection, problem identification and solution, human performance, safety conscious work environment, and other issues.

Response. The revised Reactor Oversight Process (ROP) uses insights obtained through performance indicators (PIs) along with the results of risk-informed inspections to assess licensee performance and to determine appropriate NRC actions to ensure performance issues are addressed. Performance indicators provide objective and quantifiable indication of licensee performance within each safety cornerstone. (Information on ROP performance indicators is in Enclosure 1.) However, performance indicators are not intended to be comprehensive. They are complemented by risk-informed baseline inspections performed at all operating reactor sites. Inspection results are evaluated using a process that determines the significance of the findings. In the event that a PI or inspection threshold is crossed, the NRC will take appropriate action in accordance with the defined Action Matrix (Enclosure 2). A fundamental premise of the ROP is that human performance, safety-conscious work environment, and problem identification and resolution are aspects of licensee performance that cut across all cornerstones and will be assessed either explicitly in each cornerstone through inspection or will be inferred through cornerstone performance results from both PIs and inspection results.

Wherever possible, the NRC sought to identify performance indicators as a means of measuring the performance of key attributes in each of the cornerstone areas. Where such performance indicators could not be identified, or where a performance indicator was identified but was not sufficiently comprehensive, the NRC developed baseline inspections. The NRC also identified the need for "verification" inspections to verify the accuracy and completeness of the reported performance indicator data. In addition, inspections are conducted to ensure that the causes of important events are well understood and that licensee corrective actions are adequate to prevent recurrence. Likewise, reactive inspections may be performed to follow up on allegations. The results of these follow-up inspections will be factored into the assessment process along with performance indicators and risk-informed baseline inspections.

Performance Indicators					
			Thresholds		
Cornerstone	**Indicator**		**Increased Regulatory Response Band**	**Required Regulatory Response Band**	**Unacceptable Performance Band**
Initiating Events	Unplanned Scrams per 7000 Critical Hours (automatic and manual, 4 quarter sum)		>3.0	>6.0	>25.0
	Scrams With Loss of Normal Heat Removal (12 quarter sum)		>2.0	>10.0	>20.0
	Unplanned Power Changes per 7000 Critical Hours (4 quarter sum)		>6.0	N/A	N/A
Mitigating Systems	Safety System Unavailability (12 quarter average)	**All Plants**			
		≤2 EDGs	>2.5%	>5.0%	>10.0%
		>2 EDGs	>2.5%	>10.0%	>20.0%
		Hydro emerg. power	TBD	TBD	TBD
		BWRs			
		HPCI	>4.0%	>12.0%	>50.0%
		HPCS	>1.5%	>4.0%	>20.0%
		RCIC	>4.0%	>12.0%	>50.0%
		RHR	>1.5%	>5.0%	>10.0%
		PWRs			
		HPSI	>1.5%	>5.0%	>10.0%
		AFW	>2.0%	>6.0%	>12.0%
		RHR	>1.5%	>5.0%	>10.0%
	Safety System Functional Failures (4 quarter sum)	BWRs	>6	N/A	N/A
		PWRs	>5	N/A	N/A

Performance Indicators				
		Thresholds		
Cornerstone	**Indicator**	**Increased Regulatory Response Band**	**Required Regulatory Response Band**	**Unacceptable Performance Band**
Barriers Fuel Cladding	Reactor Coolant System (RCS) Specific Activity (max monthly value last 4 quarters, % of TS Limit)	>50.0%	>100.0%	N/A
Reactor Coolant System	RCS Identified Leak Rate (max monthly value last 4 quarters, % of TS Limit)	>50.0%	>100.0%	N/A
Emergency Preparedness	Drill/Exercise Performance (% successful opportunities, 8 quarters)	<90.0%	<70.0%	N/A
	ERO Drill Participation (% of key personnel in a drill or exercise, 8 quarters)	<80.0%	<60.0%	N/A
	Alert and Notification System Reliability (% reliability, 4 quarters)	<94.0%	<90.0%	N/A
Occupational Radiation Safety	Occupational Exposure Control Effectiveness (occurrences, 4 quarter sum)	>2	>5	N/A
Public Radiation Safety	RETS/ODCM Radiological Effluent Occurrence (occurrences, 4 quarter sum)	>1	>3	N/A
Physical Protection	Protected Area Security Equipment Performance Index (4 quarters)	>0.080	N/A	N/A
	Personnel Screening Program Performance (reportable events, 4 quarter sum)	>2	>5	N/A
	Fitness-for-Duty/Personnel Reliability Program Performance (4 quarter s)	>2	>5	N/A

ENCLOSURE 2: IP2 PERFORMANCE DETAILS (INPUTS TO NRC ACTION MATRIX)

ASSESSMENT OF PERFORMANCE INDICATORS

The performance indicators for the cornerstones were in the licensee response band over the entire assessment cycle with the following exceptions:

- An Emergency Preparedness PI crossed the white threshold for drill/exercise performance based on the fourth quarter 1999 PI data. This was due to weaknesses in classifications, notifications, and protective action recommendations. Licensee-reported data for the first quarter 2000 show a return to the green range for this indicator. (PI1)
- A Mitigating Systems PI crossed the white threshold based on excessive emergency diesel generator unavailability. This was due to an improper setpoint for an Emergency Diesel Generator breaker as revealed by investigation of the August 1999 event. This PI is currently shown as green. (PI2)
- Due to the February 2000 steam generator tube failure, a Barrier Integrity PI crossed the yellow threshold based on exceeding the Technical Specification Leak Rate (ConEd Reported 109 gpm) for Steam Generator Tube Integrity. Although prior to ROP implementation, this PI data would have resulted in a degraded cornerstone in the first quarter 2000. This PI is currently shown as green. (PI3)
- An Initiating Events PI crossed the white threshold based on excessive reactor trip frequency. This was primarily due to the August 1999 automatic and the February 2000 manual reactor trips. Currently, the PI for reactor trip and unplanned power changes is shown as gray because the plant has not operated at power for a sufficient period of time for the PI to be considered valid. (PI4)

ASSESSMENT OF INSPECTION FINDINGS

NRC inspections identified and/or confirmed risk significant findings (above the green threshold) in three cornerstones: Initiating Events, Mitigating Systems, and Emergency Preparedness. These were based on applying the Significance Determination Process (SDP) to findings that were the result of licensee performance problems or issues.

- Based on inspection follow-up of the August 1999 event, there were findings of substantial safety significance for the Mitigating System Cornerstone based on the unavailability of certain auxiliary feedwater components and a degradation in feed and bleed capability. Some of the important licensee performance issues that led to these findings were the improper configuration of a Station Auxiliary Transformer Tap Changer and an improper setpoint for an Emergency Diesel Generator breaker. Although this event predated the reactor oversight process (ROP), it provided important insights about ConEd performance. This event was evaluated from a risk perspective in a feasibility study for the ROP which characterized this event as having substantial safety significance (i.e., would be a yellow issue under the ROP) due to the degradation of post accident feed and bleed capability.
- Based on NRC observations of a September 1999 exercise, an inspection finding for the Emergency Preparedness Cornerstone crossed the white threshold based on a failure to identify an improper classification during self-critique of a September exercise. (IF2)
- An inspection finding for the Initiating Event Cornerstone crossed the red threshold based on a significant increase in the likelihood of a steam generator tube rupture with a corresponding increase in Core Damage Frequency (CDF) and large early release frequency (LERF). This conclusion was based on a review of the February 2000 event which characterized the underlying problem as highly risk significant. The licensee performance issue that led to this finding resulted from poor performance during the steam generator (SG) inspections conducted during the 1997 refueling outage, and indicated weaknesses with ConEd's corrective action program. After significant evaluation, the NRC concluded that this finding was red, which places plant performance in the Multiple/Repetitive Degraded Cornerstone column of the NRC Action Matrix. (IF3)
- Three Inspection findings for the Emergency Preparedness Cornerstone crossed the white threshold because of problems associated with ERO augmentation, accountability of onsite personnel, and joint news center effectiveness. These inspection findings resulted in a degraded cornerstone. (IF4, IF5, IF6).

Exhibit 5 - ACTION MATRIX

		Licensee Response Column	Regulatory Response Column	Degraded Cornerstone Column	Multiple/ Repetitive Degraded Cornerstone Column	Unacceptable Performance Column
RESULTS		All Assessment Inputs (Performance Indicators (PIs) and Inspection Findings) Green; Cornerstone Objectives Fully Met	One or Two White Inputs (in different cornerstones) in a Strategic Performance Area; Cornerstone Objectives Fully Met	One Degraded Cornerstone (2 White Inputs or 1 Yellow Input) or any 3 White Inputs in a Strategic Performance Area; Cornerstone Objectives Met with Minimal Reduction in Safety Margin	Repetitive Degraded Cornerstone; Multiple Degraded Cornerstones; Multiple Yellow Inputs; or 1 Red Input; Cornerstone Objectives Met with Longstanding Issues or Significant Reduction in Safety Margin	Overall Unacceptable Performance; Plants Not Permitted to Operate Within this Band; Unacceptable Margin to Safety
RESPONSE	Regulatory Performance Meeting	None	Branch Chief (BC) or Division Director (DD) Meet with Licensee	DD or Regional Administrator (RA) Meet with Licensee	RA (or EDO) Meet with Senior Licensee Management	Commission meeting with Senior Licensee Management
	Licensee Action	Licensee Corrective Action	Licensee root cause evaluation and corrective action with NRC Oversight	Licensee Self Assessment with NRC Oversight	Licensee Performance Improvement Plan with NRC Oversight	
	NRC Inspection	Risk-Informed Baseline Inspection Program	Baseline and supplemental inspection procedure 95001	Baseline and supplemental inspection procedure 95002	Baseline and supplemental inspection procedure 95003	
	Regulatory Actions	None	Supplemental inspection only	Supplemental inspection only	-10 CFR 2.204 DFI -10 CFR 50.54(f) Letter - CAL/Order	Order to Modify, Suspend, or Revoke Licensed Activities
COMMUNICATION	Assessment Letters	BC or DD review/sign assessment report (w/ inspection plan)	DD review/sign assessment report (w/ inspection plan)	RA review/sign assessment report (w/ inspection plan)	RA review/sign assessment report (w/ inspection plan) Commission Informed	
	Annual Public Meeting	SRI or BC Meet with Licensee	BC or DD Meet with Licensee	RA (or designee) Discuss Performance with Licensee	EDO (or Commission) Discuss Performance with Senior Licensee Management	Commission Meeting with Senior Licensee Management
	INCREASING SAFETY SIGNIFICANCE --------->					

Note 1: The regulatory actions for plants in the Multiple/Repetitive Degraded Cornerstone column are not mandatory agency actions. However, the regional office should consider each of these regulatory actions when significant new information regarding licensee performance becomes available.

ENCLOSURE 1
INDIAN POINT 2 (April 2001 Evaluation)
SUMMARY, by Quarter, of INPUTS TO NRC ACTION MATRIX

	CY 1999		CY 2000				CY 2001		
Cornerstone	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
IE				PI4 White	IF3[1] Red	IF3 Red	IF3 Red	IF3 Red	→[3]
MS	IF1[2] Yellow	IF1 Yellow	IF1 Yellow PI2[4] White	IF1 Yellow PI2 White	→ PI2 White	→ PI2 White	→	→	→[3]
BI			PI3[4] Yellow						
EP	IF2 White	PI1[5] White IF2 White	IF2 White	IF2 White IF4 White IF5 White IF6 White	IF4 White IF5 White IF6 White	IF4 White IF5 White IF6 White	IF4 White IF5 White IF6 White	→[3]	
Matrix Column	N/A	N/A	N/A	Multiple Degraded	Multiple Degraded	Multiple Degraded	Multiple Degraded	Multiple Degraded	Multiple Degraded

[1]Classification based on event effects on CDF and LERF. NRC concluded that the tube failure was caused by a licensee performance issue.

[2]Published in the ROP "Feasibility Review," Attachment 7 to SECY 00-0049. The review of this event preceded the initiation of the Reactor Oversight Program (ROP). While the August 1999 event pre-dates the initial implementation of the ROP, useful risk insights can be derived from considering the results of the SDP for that event.

[3]In accordance with Inspection Manual Chapter 0305, this inspection finding will not be removed from consideration of future agency actions (per the Action Matrix) until the requirements of the appropriate supplemental inspection procedure have been completed.

[4]As posted on the NRC's external web page for the first quarter of 2000.

[5]In accordance with Inspection Manual Chapter 0305, if a finding and PI turn color because of the same underlying issue, only one will be counted (double jeopardy considerations).

Indian Point 2
Inspection / Activity Plan
04/01/2001 - 05/31/2002

Unit Number	Inspection Activity	Title	No. of Staff on Site	Planned Dates Start	Planned Dates End	Inspection Type
	7111105T - FIRE PROTECTION		5			
2	IP 7111105T	Fire Protection		04/09/2001	04/13/2001	Baseline Inspections
	71121 - OCC RAD SAFETY		1			
2	IP 7112101	Access Control to Radiologically Significant Areas		04/16/2001	04/20/2001	Baseline Inspections
2	IP 7112102	ALARA Planning and Controls		04/16/2001	04/20/2001	Baseline Inspections
2	IP 7112103	Radiation Monitoring Instrumentation		04/16/2001	04/20/2001	Baseline Inspections
2	IP 71151	Performance Indicator Verification		04/16/2001	04/20/2001	Baseline Inspections
	71130 - SECURITY		1			
2	IP 7113001	Access Authorization Program (Behavior Observation Only)		05/21/2001	05/25/2001	Baseline Inspections
2	IP 7113002	Access Control (Search of Personnel, Packages, and Vehicles: Identification and Authorizatior		05/21/2001	05/25/2001	Baseline Inspections
	7/9 EXAM - INIT OPER LIC EXAM		3			
2	J01427	INDIAN POINT 2 O/L INITIAL EXAM 07/09-07/13/2001		06/11/2001	06/15/2001	Not Applicable
2	J01427	INDIAN POINT 2 O/L INITIAL EXAM 07/09-07/13/2001		07/09/2001	07/13/2001	Not Applicable
	71114 - EP PROGRAM REVIEW		1			
2	IP 7111402	Alert and Notification System Testing		06/18/2001	06/22/2001	Baseline Inspections
2	IP 7111403	Emergency Response Organization Augmentation Testing		06/18/2001	06/22/2001	Baseline Inspections
2	IP 7111404	Emergency Action Level and Emergency Plan Changes		06/18/2001	06/22/2001	Baseline Inspections
2	IP 7111405	Correction of Emergency Preparedness Weaknesses and Deficiencies		06/18/2001	06/22/2001	Baseline Inspections
	95002SP - EP EXERCISE & (3) WHITE FINDINGS REVIEW		4			
2	IP 71151	Performance Indicator Verification		06/18/2001	06/22/2001	Baseline Inspections
2	IP 95002	Inspection For One Degraded Cornerstone Or Any Three White Inputs In A Strategic Performar		06/18/2001	06/22/2001	Supplemental Prograr
	71121 - OCC RAD SAFETY		1			
2	IP 7112101	Access Control to Radiologically Significant Areas		07/09/2001	07/13/2001	Baseline Inspections
2	IP 7112103	Radiation Monitoring Instrumentation		07/09/2001	07/13/2001	Baseline Inspections
2	IP 71151	Performance Indicator Verification		07/09/2001	07/13/2001	Baseline Inspections
	ENG INIT - OVERSIGHT - ENGR PROJ & RX TRIP WHITE PI		2			
2	IP 7111102	Evaluation of Changes, Tests, or Experiments		07/23/2001	07/27/2001	Other Routine
2	IP 7111117B	Permanent Plant Modifications		07/23/2001	07/27/2001	Other Routine
2	IP 95001	Supplemental Inspection For One Or Two White Inputs In A Strategic Performance Area		07/23/2001	07/27/2001	Supplemental Prograr
	7112202 - RADWASTE		1			
2	IP 7112202	Radioactive Material Processing and Transportation		10/01/2001	10/05/2001	Baseline Inspections
	SSDI - OVERSIGHT-SSFA, 8/99 YELLOW, HUMAN PERF		5			
2	IP 7111121	Safety System Design and Performance Capability		10/22/2001	10/26/2001	Other Routine
2	IP 95002	Inspection For One Degraded Cornerstone Or Any Three White Inputs In A Strategic Performar		10/22/2001	10/26/2001	Supplemental Prograr
2	IP 7111121	Safety System Design and Performance Capability		11/05/2001	11/09/2001	Other Routine

This report does not include INPO and OUTAGE activities.
This report shows only on-site and announced inspection procedures.

Indian Point 2
Inspection / Activity Plan
04/01/2001 - 05/31/2002

Unit Number	Inspection Activity	Title	No. of Staff on Site	Planned Dates Start	Planned Dates End	Inspection Type
	SSDI	**- OVERSIGHT-SSFA, 8/99 YELLOW, HUMAN PERF**	5			
2	IP 95002	Inspection For One Degraded Cornerstone Or Any Three White Inputs In A Strategic Performar		11/05/2001	11/09/2001	Supplemental Prograr
	7111112B	**- MAINT RULE**	1			
2	IP 7111112B	Maintenance Rule Implementation		10/29/2001	11/02/2001	Baseline Inspections
	71152	**- AUGMENTED PI&R, SG RED & EDG PI REVIEW**	4			
2	IP 71152	Identification and Resolution of Problems		11/26/2001	11/30/2001	Baseline Inspections
2	IP 95001	Supplemental Inspection For One Or Two White Inputs In A Strategic Performance Area		11/26/2001	11/30/2001	Supplemental Prograr
2	IP 95002	Inspection For One Degraded Cornerstone Or Any Three White Inputs In A Strategic Performar		11/26/2001	11/30/2001	Supplemental Prograr
2	IP 71152	Identification and Resolution of Problems		12/10/2001	12/14/2001	Baseline Inspections
	71121	**- OCC RAD SAFETY**	1			
2	IP 7112101	Access Control to Radiologically Significant Areas		11/26/2001	11/30/2001	Baseline Inspections
2	IP 7112103	Radiation Monitoring Instrumentation		11/26/2001	11/30/2001	Baseline Inspections
2	IP 71151	Performance Indicator Verification		11/26/2001	11/30/2001	Baseline Inspections
	7113003	**- SECURITY - RESPONSE**	2			
2	IP 7113003	Response to Contingency Events (Protective Strategy and Implementation of Protective Strate		11/26/2001	11/30/2001	Baseline Inspections
	7112201	**- RETS**	1			
2	IP 7112201	Radioactive Gaseous and Liquid Effluent Treatment and Monitoring Systems		12/17/2001	12/21/2001	Baseline Inspections
	7111117B	**- MODS**	3			
2	IP 7111102	Evaluation of Changes, Tests, or Experiments		01/14/2002	01/18/2002	Baseline Inspections
2	IP 7111117B	Permanent Plant Modifications		01/14/2002	01/18/2002	Baseline Inspections
	71121	**- OCC RAD SAFETY**	1			
2	IP 7112101	Access Control to Radiologically Significant Areas		02/04/2002	02/08/2002	Baseline Inspections
2	IP 7112102	ALARA Planning and Controls		02/04/2002	02/08/2002	Baseline Inspections
2	IP 7112103	Radiation Monitoring Instrumentation		02/04/2002	02/08/2002	Baseline Inspections
2	IP 71151	Performance Indicator Verification		02/04/2002	02/08/2002	Baseline Inspections
	SUPPLEME	**- SUPPLEMENTAL INSPECTION (IF NECESSARY)**	2			
2	IP 95002	Inspection For One Degraded Cornerstone Or Any Three White Inputs In A Strategic Performar		03/04/2002	03/08/2002	Supplemental Prograr
	71121	**- OCC RAD SAFETY**	1			
2	IP 7112101	Access Control to Radiologically Significant Areas		04/29/2002	05/03/2002	Baseline Inspections
2	IP 7112102	ALARA Planning and Controls		04/29/2002	05/03/2002	Baseline Inspections
2	IP 7112103	Radiation Monitoring Instrumentation		04/29/2002	05/03/2002	Baseline Inspections
2	IP 71151	Performance Indicator Verification		04/29/2002	05/03/2002	Baseline Inspections
	71130	**- SECURITY**	1			
2	IP 7113001	Access Authorization Program (Behavior Observation Only)		05/20/2002	05/24/2002	Baseline Inspections
2	IP 7113002	Access Control (Search of Personnel, Packages, and Vehicles; Identification and Authorizatior		05/20/2002	05/24/2002	Baseline Inspections

This report does not include INPO and OUTAGE activities.
This report shows only on-site and announced inspection procedures.

Question 4. Provide information about the quality of the plant specific risk-assessments that provide the basis for the new risk-informed regulatory approach, and whether these assessments accurately reflect the existing behavior of the plants or need to be updated.

Response. Every nuclear power plant licensee has developed a probabilistic risk assessment (PRA) to allow it to evaluate risks associated with the operation of its facility. Most licensees voluntarily update their PRAs to reflect changes in how their facilities are designed and operated. Currently, there are no NRC-endorsed quality standards for PRAs, but many licensees have subjected their PRAs to a peer review (sometimes referred to as a certification) process through an industry sponsored initiative. In addition, the NRC is working with two national standards groups to develop a PRA quality standard that is expected to be completed by the end of calendar year 2001.

The NRC reviews all proposed operating license amendments, including any supporting risk analyses. In 1998, the NRC issued regulatory guidance that is used by the NRC risk analysts to ensure that PRA quality issues are adequately addressed prior to NRC approval. The NRC's primary goal is to make good safety decisions. Such decisions rely on risk assessment results to a varying extent. That is, some decisions can be supported by a very general understanding of the risk factors; others that are broader in scope require a detailed plant-specific assessment. The NRC staff ensures that the licensee's risk analysis is of sufficient quality to support each amendment requested. Each case is supported by an NRC staff safety evaluation report. In addition, the scope of an amendment may be restricted to accommodate any perceived deficiencies in the risk analysis.

The NRC also uses probabilistic risk insights in the development and implementation of the agency's revised reactor oversight process (ROP). To assess the significance of inspection findings, senior risk analysts have been assigned to NRC headquarters and each regional office. These risk experts consider licensee comments, which can include insights from a licensee's PRA, when assessing inspection findings. If necessary, these analysts perform independent risk assessments of licensee performance issues. In addition, all risk assessments that the agency uses to evaluate licensee performance are subjected to a multi-disciplined review panel to help ensure the assessments are used in a consistent, coherent and appropriate manner.

Question 5. Describe how NRC intends to increase public confidence in NRC as an effective regulator, and ensure appropriate public participation in NRC's decision-making process.

Response. A number of activities have been initiated since the NRC identified increasing public confidence as one of the four major goals of our Strategic Plan. The NRC recognizes that effective communication is essential to instilling confidence in the agency by the general public, those we regulate, and other stakeholders. To improve communication among ourselves and with our stakeholders, the agency has launched several activities.

First, the staff have begun developing communication plans in specific program areas to assist them in communicating key messages, issues and initiatives. The plans identify points at which the public should become involved in the activity, provide guidance to the staff on the methods and tools to facilitate such involvement, and generally organize and describe NRC's contacts with stakeholders.

Second, the agency has made training available to assist the staff in planning public meetings, to emphasize the importance of improving public communication, and to communicate in clear, plain language. These courses are aimed at staff and managers who interact with the public in the course of their duties.

In order to provide an indicator of our performance in the area of increasing public confidence, the agency has instituted use of feedback forms, which are distributed to attendees at public meetings. The feedback forms gauge attendees' perceptions of how well the NRC staff presented information and responded to questions, and provide an overall assessment of the audiences' response to the effectiveness of the meeting. The agency began using the forms last October in an 18-month pilot program. At the end of the pilot program, we will assess the form's usefulness for determining trends in public confidence, as well as for identifying areas where public interactions could improve.

The agency has also begun re-designing our web site with the aim of enhancing the public's understanding of our mission, goals, and performance. The web redesign effort responds directly to stakeholders' suggestions for the site and will improve navigability and timeliness and accuracy of information. The new site will ultimately provide information that directly assists the public in their efforts to become involved in the regulatory process.

In addition, the staff has held a variety of public meetings with stakeholders over the last several years, to obtain their input and comments regarding the agency's direction in specific program areas. In April, the staff held a public meeting with interested stakeholders specifically to hear their thoughts on how the NRC might improve its public participation policies and practices. The staff is in the process of reviewing the suggestions and comments received at the meeting, and will be incorporating many of them into a report with recommendations to the Commission this summer. The report will focus on improvements to the agency's meeting processes, availability of documents to the public, and general public participation and involvement in our regulatory activities.

The agency also believes that effective communication among and between NRC staff and management is highly instrumental in building and maintaining an environment in which safety, excellence, teamwork, creativity and innovations are essential to achieving our public confidence goals. We are in the process of developing initiatives which will ultimately improve the effectiveness and efficiency of NRC's internal communications.

Question 6. Please provide an update on NRC's inspections and other activities at Indian Point 2. Does the NRC intend to increase inspections at Indian Point 2 in light of recent performance problems?

Response. Over the past few years, NRC inspection and oversight activities at Indian Point Unit 2 (IP2) have been very substantial. In May 2000, senior NRC managers concluded that the performance of the IP2 plant warranted an agency-focus classification. Later in the year, after completing an assessment of multiple inspection findings and performance indicators, including performance problems associated with the August 1999 reactor trip and February 2000 steam generator tube failure, IP2 was designated a plant with Multiple Degraded Cornerstones under NRC's revised Reactor Oversight Process. As a result, the NRC performed significant supplemental inspection of this plant. (As a result, inspection hours over the last year at IP2 have been approximately double that of any other single-unit site.)

The NRC recently completed its end-of-cycle plant performance assessment for the period of April 2, 2000 through March 31, 2001 (enclosed). Although the NRC has determined that IP2 operated in a manner that preserved public health and safety, the plant remains in the Multiple Degraded Cornerstone column of the NRC's Action Matrix. This assessment was based on results from several extensive inspections completed by the NRC, including a supplemental team review by 14 inspectors in January and February of this year. This team determined that while some performance improvements were noted, progress has been slow overall and limited in some areas. In order to verify that appropriate corrective actions have been taken to address previously identified performance issues, the NRC plans to again conduct several activities beyond the NRC baseline inspection program at the facility during this year. These activities include supplemental inspections to review progress in addressing the underlying issues that resulted in the degraded cornerstones. These focused inspections will also provide insight on the licensee's performance improvement efforts. Additionally, site visits, management meetings, and quarterly assessments will be conducted as necessary.

May 31, 2001.

MR. JOHN GROTH, *Senior Vice President,*
Nuclear Operations, Consolidated Edison Company of New York, Inc.,
Buchanan, NY.

Subject: Annual Assessment Letter—Indian Point Unit 2

Dear MR. GROTH: On May 8, 2001, the NRC staff completed its end-of-cycle plant performance assessment of Indian Point Unit 2 (IP2). The end-of-cycle review for IP2 involved the participation of all technical divisions in evaluating performance indicators (PIs) for the most recent quarter and the inspection results for the period April 2, 2000 to March 31, 2001. The purpose of this letter is to inform you of our assessment of your safety performance during this period and our plans for future inspections at your facility.

Overall, IP2 operated in a manner that preserved public health and safety. While IP2 met all cornerstone objectives, it remained in the Multiple/Repetitive Degraded Cornerstone column of the NRC's Action Matrix. The degraded cornerstones were based on several inspection findings and performance indicators in the initiating events, mitigating systems, and emergency preparedness cornerstones. These degraded cornerstones are associated principally with performance problems identified during an August 1999 reactor trip with electrical distribution system complications,

and a February 2000 steam generator tube failure (SGTF). Additionally, there were two white PIs that occurred during the assessment period in the initiating events and mitigating systems cornerstones. Enclosures 1 and 2 provide additional details regarding performance indicators and significant inspection findings for degraded cornerstones.

Several significant activities occurred over the assessment period. The plant began the assessment period in a cold shutdown condition due to the February 15, 2000, SGTF event. In August 2000, you initiated the SG replacement project which was completed in early November. The NRC noted generally good performance during SG replacement. Subsequently, the plant was readied for startup, heatup began in December, and the reactor was brought critical on December 30. Although there were some emergent issues during power escalation, the plant reached full power by the end of January. In parallel with your activities, the NRC completed a number of inspections and assessments. For example, our December 22, 2000, letter, highlighted, among other activities, system readiness walkdowns; augmented restart coverage by NRC inspectors; and inspection of emergent issues affecting design inputs and analyses, including an assessment of your corrective actions in addressing recurring issues.

During the time frame encompassing plant startup, you had a number of issues in design control, equipment reliability, problem identification and resolution, and human performance. In the area of design control, for example, a December 2000 inspection identified further examples of the lack of formal design interface controls, and weaknesses in your organization's ability to correct this condition. Equipment reliability issues were illustrated by secondary plant equipment problems which caused several power reductions in the plant restart phase. With respect to human performance, a January 2, 2001, turbine trip revealed problems with procedure quality and usage, crew communications, and reactivity management. Throughout this time frame, we monitored your corrective actions to address these issues.

In January and February 2001, an extensive supplemental team inspection was conducted by 14 inspectors using NRC Inspection Procedure 95003. The team concluded that the IP2 facility is being operated safely. The team also noted problems similar to those that have been previously identified at the IP2 facility, including those in the areas of design control, human and equipment performance, problem identification and resolution, and emergency preparedness. While some performance improvements were noted, progress was slow overall and limited in some areas. One such area is that of design control, where recurrent problems have been noted, for example, in the translation of important design assumptions into plant operating procedures, drawings, calculations, and testing programs. Also, the team noted that although some improvement in your problem identification and resolution program has occurred, aspects of your program warrant continued attention (e.g., prioritizing issues for resolution, trending causal factors, timeliness and the effectiveness of corrective actions).

While the team noted that your business plan relies heavily on department level implementation strategies that varied in quality and depth, the team found that appropriate alignment exists between the business plan and previously identified performance issues at the facility. We consider your May 7, 2001, letter captured well the nature of the issues that you are facing. We agree, as you stated in this response, that the issues facing IP2 are not amenable to "fast fixes," and that many of your improvement efforts will necessitate multi-year efforts. The NRC plans to carefully monitor the effectiveness of your performance improvement efforts, including the effect of any significant changes to your business plan or the department level activities either prior to or subsequent to any license transfer.

In order to verify that appropriate corrective actions have been taken to address the previously identified performance issues, the NRC plans to conduct several activities beyond the NRC baseline inspection program at the facility. These activities include supplemental inspections to review progress in addressing the underlying issues that resulted in the degraded cornerstones. These focused inspections will also provide insights into your performance improvement efforts. Enclosure 3 details inspections that are planned through May 31, 2002. The inspection plan is provided to minimize the resource impact on your staff and to allow for scheduling conflicts and personnel availability issues to be resolved prior to onsite arrival. Routine resident inspections are not listed due to their ongoing and continuous nature. Additionally, site visits, management meetings, and quarterly assessments, will be conducted as necessary. In this regard, we conducted a meeting on April 30, 2001, focused principally on design and engineering issues.

Consistent with the Reactor Oversight Process, we are finalizing plans to meet with you to discuss NRC's assessment of your performance, and your continuing actions to effect performance improvement at IP2. This meeting, which will be open

for public observation, is scheduled for 7 p.m., June 13, 2001, at the Energy Education Center. Additionally, consistent with guidance in the NRC Action Matrix, the NRC considered the need for additional regulatory actions beyond those described herein, and has concluded that none are required at this time. The staff will continue to consider the appropriateness of additional regulatory actions as new performance information becomes available. Finally, in accordance with IMC 0305, "Operating Reactor Assessment Program," IP2 will be discussed at the upcoming Agency Action Review meeting. We will notify you via separate correspondence if any agency actions change, as an outcome of this meeting.

For your information, the NRC is in the process of aligning the inspection and assessment cycle with the calender year. In order to transition to a calender year cycle (January 1-December 31), the next inspection and assessment cycle will consist of only three quarters (i.e., the second, third and fourth calender quarters of CY 2001). As a result, for all plants a quarterly review will be conducted for the third calender quarter (July 1- September 30) in lieu of a mid-cycle review.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room). To get information about the assessment terms used in this document refer to NRC's program for overseeing the safe operation of commercial nuclear power reactors. It is described in the NRC Reactor Oversight Process web site at http://www.nrc.gov/NRR/OVERSIGHT/index.html.

If circumstances arise which cause us to change this inspection plan, we will contact you to discuss the change as soon as possible. Please contact Mr. Peter Eselgroth at 610–337–5234 with any questions you may have regarding this letter or the inspection plan.

Sincerely,

HUBERT J. MILLER,
Regional Administrator.

RESPONSES BY RICHARD MESERVE TO QUESTIONS FROM SENATOR CORZINE

Question 1a. I am concerned about the revised regulations governing nuclear medicine in 10 CFR Part 35 that are now under review at OMB. You cited these revisions in your testimony as a success story in the NRC's efforts to use risk to guide regulations. Yet a 1996 National Academy of Sciences/Institute of Medicine study concluded that revisions to the reporting and enforcement systems along the lines you have proposed would result in negligible decreases in risks to health care providers and patients. On the other hand, I understand that the estimated costs of your revised regulations run as high as $500 million. On the basis of these facts, I am concerned that your changes to these regulations will unnecessarily expend scarce health resources.

Please provide a summary of both the methodology and the results of the risk assessments that informed the revisions to 10 CFR Part 35 that are now under review at OMB.

Response. The Commission's revisions to Part 35 were developed after the National Academy of Sciences, Institute of Medicine (NAS–IOM) Report was published in 1996 and used risk information developed by NAS–IOM in formulating the revised requirements. That is, Part 35 now pursues a risk-informed approach which decreased the burden for those types of medical activities which pose a low risk to health care providers, members of the public, and patients. Conversely, requirements have been strengthened for those activities that pose a more significant risk in order to assure the safe handling of NRC-regulated nuclear materials in a medical setting. The figure of $500 million for the cost of the revised regulation is not an NRC estimate. The final Regulatory Analysis prepared by the NRC for the 10 CFR Part 35 rulemaking examines the difference in the cost of compliance with the revised regulation with the cost of compliance with the existing regulation. That estimate shows a net reduction of $8,836,000 per year for licensees in NRC and Agreement States as a result of the revised regulations.

A formal risk assessment was not conducted. In determining that a formal risk assessment would not be conducted, the Commission was aware that the data necessary to perform a relative risk assessment may not be available. The National Academy of Sciences, Institute of Medicine (NAS–IOM) Report on Radiation in Nuclear Medicine: A Need for Regulatory Reform (National Academy Press, 1996) included risk assessment information, as well as a discussion of the comparative risk

of ionizing radiation in medicine to risks in other medical modalities (Chapter 4). The NAS–IOM report concluded that "no comprehensive raw data are available to make exact comparisons" between risks of medical modalities (pg. 124). The report recognized that quantifying levels of risk in radiation medicine is problematic (pg. 128). The Commission's Advisory Committee on the Medical Uses of Isotopes also recognized that quantifying levels of risk in radiation medicine is problematic in a May 8, 1997 Commission briefing.

The Commission opted to restructure 10 CFR Part 35 into a more risk-informed, more performance-based regulation by focusing on those medical procedures that pose the highest risk from a radiation safety standpoint. At the Commission's direction, the NRC staff carefully considered the risk information in several extensive assessments, including the external review conducted by NAS–IOM, a 1993 NRC internal senior management review and report, and the Commission's Strategic Assessment and Rebaselining initiative. This information, along with the information in the NRC's event databases and the input received during the enhanced rulemaking participatory process, was used to determine the requirements that are necessary to ensure radiation safety during the medical use of byproduct material. Consideration of all of this information resulted in reduction of regulatory burden by eliminating or decreasing the prescriptiveness of various requirements that apply to the lower-risk area of diagnostic medical procedures.

Question 1b. Please explain why the conclusions of the 1996 NAS/IOM study were apparently disregarded in your revision of 10 CFR Part 35.

Response. The National Academy of Sciences, Institute of Medicine (NAS–IOM) study was conducted because NRC sought an evaluation of whether the rules, policies, and procedures of the current regulatory framework for medical uses of byproduct material fulfilled the NRC's statutory responsibilities for public health and safety. The Commission was not persuaded by the NAS–IOM report's overall recommendation to Congress, that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine, based, in part, on comments received from some State and Federal agencies. For example, the Food and Drug Administration, to which additional responsibility would have fallen if the NRC adopted the recommendation, indicated that it did not support the recommendation. The Commission continues to believe that the conclusions in the report were not substantiated and that this particular recommendation should not be pursued.

The report was not rejected on the basis of its analysis of risks of ionizing radiation in medicine. In fact, the risk assessment information in the report, including the information on comparative risks of ionizing radiation in medicine, was considered during the rulemaking process. As stated above, the NAS report concluded that "no comprehensive raw data are available to make exact comparisons" between risks of medical modalities (pg. 124), and it recognized that quantifying levels of risk in radiation medicine is problematic.

Question 1c. Please provide any cost-benefit analyses that you developed in support of the revisions to 10 CFR Part 35.

Response. The Final Regulatory Analysis for the 10 CFR Part 35 rulemaking analyzes the regulatory burden for the revised regulation and compares it to the regulatory burden for the existing 10 CFR Part 35. This analysis concluded that the revisions to 10 CFR Part 35 will result in a total annual cost savings of $8,836,000 to medical licensees in NRC and Agreement States (pg. 6–5). In addition to the cost savings, benefits of the revisions to Part 35 include more focused and more performance-based requirements for the implementation of the Quality Management program, specific necessary training for different types of medical treatment such as high dose rate brachytherapy, and reporting of medical events to NRC. Copies of the Final Regulatory Analysis are being provided with the response to this question.

FINAL REGULATORY ANALYSIS; 10 CFR PARTS 20, 32, AND 35; COMPREHENSIVE REVISION OF 10 CFR PART 35; "MEDICAL USE OF BYPRODUCT MATERIAL" AND PETITION FOR RULEMAKING; "REVISION OF DOSE LIMIT FOR MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED PATIENTS"; (PRM–20–24); AMENDING 10 CFR PART 20 "STANDARDS FOR PROTECTION AGAINST RADIATION"; AND CONFORMING AMENDMENT TO 10 CFR PART 32; "SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL"

1. BACKGROUND

10 CFR Part 35

NRC's Medical Use Program includes uses of byproduct material in medical diagnosis, therapy, and research. There are approximately 1,655 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35. There are approximately 4,138 State licenses in Agreement States authorizing the medical use of byproduct material. It's estimated more than twelve million patients annually have nuclear medicine procedures involving byproduct materials.[1] Use of teletherapy, brachytherapy, and gamma stereotactic radiosurgery for treatment involves more than half-a-million patients annually.[2]

During the last 6 years, the Nuclear Regulatory Commission (NRC) has examined the issues surrounding its regulations governing the medical use of byproduct material (10 CFR Part 35), and now is enacting a comprehensive revision of those regulations.

The NRC's reexamination of 10 CFR Part 35 began in 1993 with an internal senior management review report prepared by NRC. NRC then sponsored an external study, conducted between January 1994 and 1996, by the National Academy of Sciences, Institute of Medicine. 10 CFR Part 35 also was addressed in NRC's Strategic Assessment and Rebaselining Project (SA), culminating in the SA Direction-Setting Issue Paper Number 7 (DSI 7) released September 16, 1996. On March 20, 1997, the Commission issued a Staff Requirements Memorandum (SRM) ("COMSECY–96–057, Materials/Medical Oversight (DSI 7)") directing the staff to revise 10 CFR Part 35 to restructure it into a more risk-informed, more performance-based regulation.

On August 13, 1998, NRC published proposed revisions to 10 CFR Part 35 in the Federal Register (63 FR 43516). The public comment period on this proposed rule expired on November 12, 1998. The NRC subsequently reopened the public comment period until December 16, 1998 (63 FR 64829). The NRC staff reviewed the public comments and evaluated possible changes to the proposed rule. On March 25, 1999, the staff and members of the Advisory Committee on Medical Uses of Isotopes briefed the Commission on the public comments and the proposed responses to the comments.

In a Staff Requirements Memorandum (SRM) dated April 23, 1999, the Commission requested that staff provide it with a paper providing draft final rule text and those portions of the statements of consideration that discuss resolution of public comments and provide enough information to allow comparison of the changes from the current rule to the proposed rule and the draft final rule. In a SRM dated February 16, 2000, the Commission requested the NRC staff incorporate specific changes to the draft final rule language and responses to public comments.

10 CFR Part 20

At the same time that it is revising Part 35, the NRC also is amending its regulations in 10 CFR Part 20, Standards for Protection Against Radiation, in response to a Petition for Rulemaking (PRM–20–24) dated April 7, 1996, from the University of Cincinnati. PRM–20–24 requests NRC to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up

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[1] A survey performed for the Society of Nuclear Medicine in 1993 estimated that about 10.7 million procedures were performed annually. Clouse, J.C., Rogers, M., Carretta, R.F., et al., Future Nuclear Medicine Physician Requirements, J. Nucl. Med., May 1996 (37:5), 14N–18N (Figures 2 and 3). A more recent estimate places the number of procedures in 1997 at about 12.9 million. (Communication with Dr. M. Polycove, September 1999).

[2] Estimate based on estimated number of new cancer cases treated with radiation provided by the American Cancer Society to the National Academy of Sciences, Institute of Medicine, National Academy of Sciences, Radiation in Medicine, Washington, DC, 1996, 65–67. Tabulations by the American College of Radiology of Medicine data (Part B Medicare Annual Data) for 1997 show approximately 33,000 brachytherapy procedures and approximately 75,000 cobalt teletherapy applications for Medicare patients. As a general rule, the total for all Americans is approximately 3 times the Medicare total or about 100,000 brachytherapy and approximately 225,000 teletherapy procedures. However, this 3 to 1 approximation is less accurate for quite specific procedures, as here, than it is for broad ranges of health care services.

to 5 mSv (0.5 rem) per year, rather than the current limit of 1 mSv (0.1 rem) in 10 CFR 20.1301.

The 1991 revision of 10 CFR Part 20 (56 FR 23398; May 21, 1991) established a public dose limit of 1 mSv (0.1 rem) per year (10 CFR 20.1301(a)). 10 CFR 20.1301(c) permits licensees to request NRC authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) per year. However, fewer than 10 medical licensees have applied for such an NRC authorization for visitors since the 1991 revision. Under 10 CFR 35.75(a), a licensee who is an authorized user of byproduct materials for medical use may authorize the release from its control of any patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from the released patient is not likely to exceed 5 mSv (0.5 rem).

The petitioner in PRM–20–24 requested that the NRC amend 10 CFR 20.1301 to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive up to 5 mSv (0.5 rem) per year. The petitioner argued that the higher dose limit is appropriate for visitors determined by the physician to be necessary for the emotional or physical support of the patient (e.g., parents of very young radiation therapy patients, close family members of elderly patients, or other persons who could provide emotional support to the patient).

The proposed revision to Part 20 was published in the Federal Register on August 13, 1998 (63 FR 43516). The public comment period on the proposed rule ended December 16, 1998.

10 CFR Part 32

References to certain sections of Part 35 contained in Part 32 are being revised to conform Part 32 to the revisions in Part 35.

1.1 Statement of the Problem

10 CFR Part 35

NRC has identified the following six problems that require revisions to 10 CFR Part 35. [3]

First, revisions are needed to address the unnecessarily overly prescriptive nature of specific sections of 10 CFR Part 35 that result in costs to licensees without commensurate health and safety benefits. Although licensees currently have the option of adopting alternative measures, this requires a license amendment. License amendments are costly both to the licensee and to NRC.

Second, revisions are needed to place the basis for regulation of certain well-established technologies into 10 CFR Part 35. Specifically, the regulations in 10 CFR Part 35 currently do not address high dose-rate remote brachytherapy, low dose-rate remote brachytherapy, pulsed dose-rate remote brachytherapy, and gamma stereotactic radiosurgery. The regulatory basis for these technologies currently is established by license conditions rather than regulations.

Third, revisions are needed to provide for the incorporation of new technologies in a timely manner. Currently, new technologies must be licensed through case-by-case reviews in which the applicant or licensee must submit a request for an exemption for technologies not specifically addressed in 10 CFR Part 35.

Fourth, the regulations in § 35.2, regarding thresholds for misadministrations, are not entirely dose based. These regulations do not address new technologies or patient intervention, nor do they provide a threshold for wrong treatment site. Further, the Commission directed the staff to consider changing the nomenclature from "misadministration" to "medical event."

Fifth, the requirements in Subpart J, concerning training and experience, include requirements for clinical experience in all modalities. Because diagnostic procedures present a lower overall risk, as compared to therapeutic procedures, most of the supervised clinical experience currently required may not be necessary for most diagnostic uses.

Sixth, the regulations now permit medical use licensees to hold byproduct material with a half-life less than 65 days for decay-in-storage for a minimum of ten half-lives before disposal in ordinary trash. Licensees now must obtain a license amendment exempting them from the requirements of § 35.92 for materials with longer half-lives or to hold material for less than ten half-lives.

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[3] The Commission, in its Staff Requirements Memorandum (SRM)–COMSECY–96–057 dated March 20, 1997, also directed the NRC staff to consider a seventh issue, the best way to capture not only relevant safety-related events, but also precursor events. After detailed consideration, including comments from a wide variety of stakeholders and the public, proposals for addressing precursor events were not adopted for the final rule.

10 CFR Part 20

Revisions to 10 CFR Part 20 are required because the 100 mrem public dose limit in 10 CFR 20.1301(c) is overly restrictive with respect to visitors to patients undergoing therapy involving byproduct material. This is a problem because there are occasions when additional access to the radiation therapy patient by family or friends, as determined by the authorized user physician, is necessary to provide both physical and emotional support while the patient is under licensee control.

10 CFR Part 32

Revisions to 10 CFR Part 32 are required to conform references to Part 35 in Part 32 to the revised Part 35.

1.2 Earlier NRC Actions

10 CFR Part 35

The NRC published an announcement of its program for revision of 10 CFR Part 35 and a request for public input on the rule development in a document published in the Federal Register on August 6, 1997 (62 FR 42219). The NRC staff adopted a modality approach to the 10 CFR Part 35 rule. The final rule addresses the following modalities: (1) unsealed byproduct material—written directive not required; (2) unsealed byproduct material—written directive required; (3) manual brachytherapy; (4) sealed sources for diagnosis; (5) photon emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units; and (6) other medical uses of byproduct material or radiation from byproduct material.

Development of the text of the final rule as well as draft guidance documents was done by a governmental Working Group and a Steering Group. Representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors, Inc. were members of both the Working Group and the Steering Group.

The NRC convened or participated in a number of public workshops and meetings to discuss the fundamental approaches and issues to be addressed in the rulemaking. These workshops and meetings were intended to ensure that the interests affected by the medical use rulemaking were given an early opportunity to comment on the rulemaking issues and to discuss the rulemaking issues with one another and the NRC. NRC participated in a workshop held during the Organization of Agreement States' 1997 All Agreement States meeting on October 18, 1997 in Los Angeles, California. (See 62 FR 52513; October 8, 1997). The All Agreement States meeting was attended not only by representatives of the 30 Agreement States but also by the public. NRC convened two facilitated public workshops, in Philadelphia, Pennsylvania on October 28, 29, and 30 and in Chicago, Illinois on November 12, 13, and 14, 1997. (See 62 FR 53249; October 14, 1997). These workshops were attended by nuclear medicine physicians; radiation oncologists; other specialists (e.g., cardiologists and radiologists); medical physicists; medical technologists; nurses; medical education and certification organizations; radiopharmaceutical interests; hospital administrators; patients' rights advocates; Agreement States; Federal agencies; and members of the public. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an NRC advisory committee, discussed the issues regarding the revision of 10 CFR Part 35 in its meetings on September 25 and 26, 1997 and March 1 and 2, 1998. Finally, NRC staff attended meetings with numerous groups representing physicians, pharmacists, medical physicists, technologists, and other stakeholders.

The two facilitated workshops sponsored by the NRC, as well as NRC's participation in other meetings, were intended to foster a clearer understanding of the positions and concerns of the affected interests, and were not intended to develop a consensus agreement of the participants on the rulemaking issues. However, the proposed rule was the evolutionary result of these numerous meetings, as well as the reasoned consideration of the Working Group and Steering Group.

Following the August 13, 1998, publication of the proposed rule, NRC convened three facilitated workshops during the public comment period on the proposed rule to provide an opportunity for the affected interests and other members of the public to discuss the proposed rule. (These meetings were held in San Francisco, California on August 19 and 20, 1998; in Kansas City, Missouri on September 16 and 17, 1998; and in Rockville, Maryland on October 21 and 22, 1998.) In addition, NRC staff attended a meeting of the Association of Agreement States held on October 31, 1998. NRC staff also met with members of medical specialties boards on February 17–18, 1999. A Diagnostic Subcommittee of the ACMUI met in Rockville, Maryland on February 23–24, 1999, and a Therapeutic Subcommittee of the ACMUI met in Rockville, Maryland on February 25–26, 1999, to discuss issues raised by the Part 35

rulemaking. A meeting of the full ACMUI to discuss the Part 35 rulemaking was held on March 24–25, 1999.

10 CFR Part 20

The analysis of PRM–20–24 began on June 21, 1996 (61 FR 31874), when the NRC published a notice of receipt and a request for comment on the petition. All commenters agreed with the petitioner that it was unreasonable to require licensees to limit doses to specified visitors to the public dose limit of 1 mSv (0.1 rem). A draft rulemaking plan was prepared and provided to the Agreement States on May 1, 1997, for review and comment, and a final rulemaking plan was submitted to the Commission for approval on August 1, 1997. The NRC consolidated action on PRM–20–24 with the 10 CFR Part 35 rulemaking in January, 1998.

2. OBJECTIVES OF THE RULEMAKING

10 CFR Part 35

In its "Staff Requirements Memorandum (SRM)–COMSECY–96–057, Materials/Medical Oversight (SDI 7)," dated March 20, 1997, the Commission directed the staff to revise 10 CFR Part 35; associated guidance documents; and, if necessary, the Commission's 1979 Medical Policy Statement. The Commission's SRM specifically directed the restructuring of 10 CFR Part 35 into a more risk-informed, more performance-based regulation. During development of the final rule and associated guidance as well as during review of the Medical Policy Statement, the NRC staff was directed to consider the following issues:

(1) Focusing 10 CFR Part 35 on those procedures that pose the highest risk;

(2) Regulatory oversight alternatives for diagnostic procedures that are consistent with the lower overall risk of these procedures;

(3) The best way to capture not only relevant safety-significant events, but also precursor events;

(4) The need to change from the term "misadministration" to "medical event" or other comparable terminology;

(5) Redesigning 10 CFR Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner;

(6) Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety (e.g., confirming patient identity requiring written directives, and verifying dose; and

(7) The viability of using or referencing available industry guidance and standards, within 10 CFR Part 35 and related guidance, to the extent that they meet NRC's needs.

In carrying out these objectives, the NRC also sought the following:

- Restructuring 10 CFR Part 35 to incorporate a modality-based approach;
- Reducing or eliminating duplication or overlaps between 10 CFR Part 35 and other Parts of 10 CFR, particularly 10 CFR Part 20; and
- Reducing recordkeeping and/or reporting requirements whenever possible.

10 CFR Part 20

The objective of the rulemaking to address PRM–20–24 is to permit authorized user physicians the discretion to permit specified visitors to receive doses in excess of the 1 mSv (0.1 rem) public dose limit in order to provide physical and emotional support to hospitalized individuals administered radioactive materials or radiation from byproduct materials.

3. ALTERNATIVES

The following alternatives were considered in this analysis:

Alternative One:

10 CFR Part 35: Continue 10 CFR Part 35 without revision.

10 CFR Part 20: Deny PRM–20–24 and retain the 1 mSv (0.1 rem) public dose limit for visitors of radiation therapy patients on the basis that there are sufficient provisions within 10 CFR 20.1301(c) to allow case-by-case use of the 5 mSv (0.5 rem) annual dose limit for visitors of radiation patients.

10 CFR Part 32: Continue 10 CFR Part 32 without revision.

Alternative Two:

10 CFR Part 35: Promulgate comprehensive revisions to 10 CFR Part 35 that relax certain prescriptive requirements currently contained in 10 CFR Part 35 with respect to Radiation Safety Committees, quality management, training and experience, reporting and recordkeeping, and other requirements currently covered by both 10 CFR Part 35 and 10 CFR Part 20. Substitute new requirements with re-

spect to training and experience. Incorporate new requirements for therapeutic uses of radionuclides, including requirements for remote afterloaders, and gamma stereotactic radiosurgery.

10 CFR Part 20: Promulgate a new dose limit of 5 mSv (0.5 rem), as requested under PRM–20–24, including a requirement to provide basic radiation safety instruction for specified visitors of radiation therapy patients, but no requirement for visitor badging or recordkeeping.

10 CFR Part 32: Promulgate conforming changes to reflect changes to 10 CFR Part 35.

The staff selected alternative two as the preferred option.

4. UNDERLYING DATA AND ASSUMPTIONS

The following data and assumptions were used to evaluate the values and impacts of the alternatives for revisions to 10 CFR Part 35 and response to PRM–20–24.

4.1 Number and Type of Licensees

Table 1 provides data from NRC's License Tracking System on the number of NRC 10 CFR Part 35 licensees, by category, as of July 1999. The number of Agreement States licensees is estimated at 2.5 times the number of NRC licensees, based on discussions with cognizant staff of the NRC Office of State and Tribal Programs. Estimates throughout are based on the assumption that Agreement States will adopt all of the regulatory changes.

Table 1.—Number and Type of Licenses

	Program Code [1]	NRC [2]	Agreement States [3]
Numbers and Types of Medical Licensees:			
Medical Institution-Broad	2110	74	185
Medical Institution-QMP Req	2120	767	1,919
Medical Institution-QMP Not Req	2121	135	338
Medical Private Practice-QMP Req	2200	133	333
Medical Private Practice-QMP Not Req	2201	325	813
Eye Applicators Strontium–90	2210	20	50
Mobile Nuclear Medicine Service	2220	44	110
High Dose-Rate Remote Afterloader	2230	97	243
Medium and Low Dose-Rate Remote Afterloader		[4] 24	[4] 60
Pulse Dose-Rate Remote Afterloader		0	[5] 35
Mobile HDR Remote Afterloader	2231	4	[6] 3
Mobile Therapy	2240	0	0
Teletherapy	2300	17	43
Gamma Stereotactic Radiosurgery	2310	15	38
Total		1,655	4,138

[1] NRC Material License Program Codes.
[2] Data from NRC License Tracking System (LTS), February 2001.
[3] Estimated, based on 1 to 2.5 ratio of NRC licensees to Agreement States licensees.
[4] Not based on NRC License Tracking System; estimated based on information supplied by ACMUI, March 2, 1998. These data constitute upper bound estimates, due to shifts from use of LDR to HDR when feasible.
[5] Estimated, based on information supplied by ACMUI, March 2, 1998.
[6] Estimated, based on information supplied by NRC Office of State and Tribal Programs.

4.2 General Administrative Activities

Table 2 provides estimates of the numbers of activities or persons subject to the general administrative requirements of 10 CFR Part 35, such as Radiation Safety Officers, meetings of Radiation Safety Committees, and license amendments under 10 CFR Part 35. It also provides estimates of the number of individuals per year becoming authorized users, authorized nuclear pharmacists, Radiation Safety Officers, or medical physicists for the first time.

Table 2.—General Administrative Activities

	NRC	Agreement States
Number of Radiation Safety Officers [1]	1,655	4,137
Number of Medical Institutions with Quality Management Plans [2]	1,166	2,014
Number of License Amendments Completed Annually [3]	1,655	3,310

	NRC and Agreement States
Number of individuals per year[4] seeking certification for:	
Uptake, Dilution, and Excretion Studies	110
Imaging and Localization Studies	110
Therapeutic Unsealed Sources	100
Oral administration of sodium iodide I–131	100
Ophthalmic use of Strontium–90	15
Brachytherapy	150
Sealed Sources for Diagnosis	80
Therapeutic Medical Devices	150
Nuclear Pharmacist	20
Medical Physicist	100

[1] Estimated for current rule, based on regulatory requirement that all licensees must appoint an RSO.

[2] Total of program codes 2110, 2120, 2200, 2210, 2230, 2231, 2240, 2300, and 2310 for NRC licensees. Agreement States estimate adjusted to reflect the proportion of Agreement States (9 of 30, according to data provided by the NRC Office of State and Tribal Programs in 1998) that have not adopted a quality management rule.

[3] Estimated as one amendment per year per licensee for current rule for NRC licensees and one amendment per year for 80 percent of Agreement State licensees. This represents an upper bound estimate. According to NRC's final rule promulgating fee schedules for fiscal year 1999, not all materials licensees request amendments during a given fiscal year. Over a 5-year period, approximately 80 percent request at least one amendment, and approximately 40 percent request multiple amendments. (64 FR 31460; June 10, 1999)

[4] Compiled from estimates (in some cases covering a period of 5 or more years of data) obtained from American Board of Radiology, American Board of Nuclear Medicine, American Board of Medical Physicists, Health Physics Society, Board of Pharmaceutical Specialities and from personal communications with Barry Siegel, M.D., Mr. Mark Rotman, and NRC staff. Published sources include American Board of Radiology, ABR Examiner, 2:1 (Examination Statistical Summary 1991–1996) and 4:1 (Examination Statistical Summary 1994–1998); Society of Nuclear Medicine, Journal of Nuclear Medicine, Newsline: The SNM Manpower Survey Report, 33:11 (November 1992), Newsline: Future Nuclear Medicine Physician Requirements, 37:5 (May 1996), and Newsline: Future of Nuclear Medicine, Part 3: Assessment of the U.S. Therapeutic Radiopharmaceuticals Market (2001–2020), 39:7 (July 1998): and The Official ABMS Directory of Board Certified Medical Specialists, 1997 and 1999.

4.3 Current Uses of Byproduct Materials

Since 1946, growth in the medical applications of radioisotopes has been very rapid as their usefulness has become more apparent in diagnosis, therapy, and medical research. Current medical procedures employ a number of radionuclides in a wide variety of chemical and physical forms. Nuclear medicine procedures for diagnostic and therapeutic applications involve the internal administration of radiolabeled tracers. Administration of the radiolabeled tracers, known as radiopharmaceuticals, may be performed by intravenous injection, inhalation, or oral ingestion. In most cases, diagnostic nuclear medicine involves imaging agents used for the delineation and localization of organ tissues by scintigraphy (e.g., technetium–99m hydroxymethylene diphosphonate used as a bone seeking radiopharmaceutical). Organ function may be determined by quantifying the accumulation of radiopharmaceuticals in organs of interest (e.g., iodine–131 uptake studies used to assess thyroid function). Therapeutic nuclear medicine may use various radiopharmaceuticals for the treatment of disease by selective absorption or concentration (e.g., iodine–131 used to treat thyroid cancer). Other therapeutic applications may involve the use of radiopharmaceuticals in colloidal suspensions for the treatment of malignant tumors (e.g., phosphate–32 infusion for treatment of peritoneal or pleural effusions associated with malignant tumors).

Since the early 1900s, radiation therapy has become one of the major modalities of treatment in the management of neoplastic disease, generally referred to as cancer. Radiation therapy may also be used as a palliative agent in the medical treatment process. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tumor volume. This is usually accomplished by delivering a dose in daily increments over several weeks. External beam radiation therapy has evolved using innovative technology that has led to the development of the gamma stereotactic radiosurgery device used for treatment of precisely defined intracranial targets (e.g., brain tumors and arteriovenous malformations).

Brachytherapy uses a variety of smaller sealed sources for localized treatment of cancer. Typically the sealed sources are either inserted in a cavity (e.g., cesium–137 sources used for intracavitary treatment of cervical cancer) or implanted in tissue (e.g., iodine–125 seeds used for interstitial treatment of prostate cancer). Various remote afterloading devices have been developed for low, medium, and high dose-rate brachytherapy treatments.

5.0 REVISIONS TO REGULATORY TEXT AND CONSEQUENCES

SUBPART A—GENERAL INFORMATION

5.1 Purpose and scope (§ 35.1).

Section 35.1 currently provides that 10 CFR Part 35 contains requirements for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of public health and safety.

The final rule substitutes the words "radiation safety of workers, the general public, patients, and human research subjects" for "protection of the public health and safety." The final rule adds Part 171 to the list of Parts that apply to applicants and licensees subject to Part 35.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Provides improved clarity and precision as well as consistency with revisions to the Medical Policy Statement.

5.2 Definitions (§ 35.2).

Section 35.2 sets out the applicable definitions for 10 CFR Part 35.

The final rule deletes the definitions of "ALARA," "Dental use," "Diagnostic clinical procedures manual," "Mobile nuclear medical service," "Ministerial change," "Misadministration," "Podiatric use," "Recordable event," and "Teletherapy physicist."

The final rule revises the definitions of "Area of use," "Authorized nuclear pharmacist," "Authorized user," "Brachytherapy source," "Management," "Medical use," "Output," "Prescribed dosage," "Prescribed dose," "Radiation Safety Officer," and "Written directive."

The final rule adds definitions for "Authorized medical physicist," "Brachytherapy," "Client's address," "High dose-rate remote afterloader," "Low dose-rate remote afterloader," "Manual brachytherapy," "Medical event," "Medium dose-rate remote afterloader," "Mobile Medical service," "Patient intervention," "Preceptor," "Pulsed dose-rate remote afterloader," "Sealed Source and Device Registry," "Stereotactic radiosurgery," "Structured educational program," "Teletherapy," "Temporary jobsite," "Therapeutic dosage," "Therapeutic dose," "Treatment site," "Type of use," and "Unit dosage."

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Provide improved clarity and precision.

5.3 Maintenance of records (§ 35.5).

Section 35.5 specifies that records required by Part 35 must be legible throughout the retention period. It specifies that the record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of providing a clear copy throughout the required retention period. It also specifies that the record may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. The final rule revises the phrase "Records such as letters, drawings, specifications, must include all pertinent information . . . " to read "Records such as letters, drawings, and specifications . . . ."

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Improved clarity.

5.4 Provisions for the protection of human research subjects (§ 35.6).

Section 35.6 provides that a licensee may conduct research involving human subjects using byproduct material if requirements specified in the section are met.

Section 35.6(a) of the final rule provides that a licensee may conduct research involving human research subjects only if using the byproduct materials specified on its license for the uses authorized on its license.

Section 35.6(b) of the final rule requires that if the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research, obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy and obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

Section 35.6(c) of the final rule requires that if the research is not conducted, funded, supported, or regulated by another Federal agency that has implemented

the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research, obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy and obtain "informed consent," as defined and described in the Federal Policy, from the research subject.

Section 35.6(d) of the final rule clarifies that nothing in this section relieves licensees from complying with the other requirements in Part 35 and that all relevant radiation safety provisions of Part 35 are applicable to research involving human subjects.

Cost Impacts: None anticipated.
Health and Safety Impacts: None anticipated.
Benefits: Improved clarity.

5.5 FDA, other Federal, and State requirements (§ 35.7).

Section 35.7 provides that nothing in Part 35 relieves a licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

The final rule amends the section to provide that licensees are required to comply with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

Cost Impacts: None anticipated.
Health and Safety Impacts: None anticipated.
Benefits: Improved clarity.

5.6 Information collection requirements: OMB approval (§ 35.8).

Section 35.8(a) specifies the OMB-approved information collection requirements contained in 10 CFR Part 35, and specifies that OMB has approved the information collection requirements in this 10 CFR Part under control number 3150–0010.

The final rule changes section numbers in § 35.8(b) to conform with the final rule.

Section 35.8(c) of the final rule adds NRC Forms 313A and 313B to the information collection approved under control number 3150–0120 for § 35.12.

The final rule deletes § 35.8(d) referring to OMB control number 3150–0171, which covered the information collection requirements contained in §§ 35.32 and 35.33, which are eliminated in the final rule.

Cost Impacts: None anticipated.
Health and Safety Impacts: None anticipated.
Benefits: Conforming change for restructuring of 10 CFR Part 35.

5.7 Implementation (§ 35.10).

The final rule adds a new section, § 35.10, that provides implementation schedules.

Section 35.10(a) requires licensees to implement the provisions in 10 CFR Part 35 on or before six months from publication of the final rule.

Section 35.10(b) allows licensees currently exempted from a provision in the current 10 CFR Part 35 to continue to be exempt under the final regulations.

Section 35.10(c) provides that if a requirement in an existing license condition differs from a requirement in the current 10 CFR Part 35, the requirements in Part 35 govern.

Section 35.10(d) requires licensees to continue to comply with any license conditions that requires them to implement procedures required by §§ 35.610, 35.642, 35.643 and 35.645.

Cost Impacts: None anticipated.
Health and Safety Impacts: None anticipated.
Benefits: Provides licensees time to implement new requirements.

5.8 License required (§ 35.11).

Section 35.11(a) currently provides that a person may not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b) or (c) of § 35.11. Section 35.11(b) currently specifies that an individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in 10 CFR Part 35 under the supervision of an authorized user, as specified in the requirements on supervision in § 35.25, unless prohibited by license condition. Section 35.11(c) currently provides that an individual may prepare unsealed byproduct material for medical use in accordance with the regulations in Part 35 under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.25, unless prohibited by license condition.

Section 35.11(a) of the final rule provides that a person may manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use only in accordance with a specific license or as allowed in §§ 35.11(b)(1) or (b)(2) of this section.

Section 35.11(b) of the final rule provides that a specific license is not needed for an individual who receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition, or for an individual who prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition. Section 35.11(b)(2) incorporates the provisions currently included in § 35.11(c).

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Improved clarity.

5.9 Application for license, amendment, or renewal (§ 35.12).

Section 35.12 of the current rule specifies the procedures for license application, amendment, or renewal.

Section 35.12(a) currently specifies that if the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

Sections 35.12(b) and (c) currently specify that an application for medical use of byproduct material as described in the pertinent sections of 10 CFR Part 35 must be made by filing Form NRC–313.

The final rule provides in § 35.12(a) that the application must be signed by the applicant's or licensee's management and eliminates the reference to application by "any person."

In § 35.12(b), the final rule adds a reference to § 35.600, which in the final rule addresses remote afterloader units and gamma stereotactic radiosurgery units, and § 35.1000, which in the final rule addresses medical uses not covered by §§ 35.100 through 35.600. Section 35.12(b)(2) of the final rule requires the submission of procedures mandated by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

Section 35.12(c) specifies that a request for a license amendment or renewal must be made by submitting an original and one copy in letter format and submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

The final rule adds a new § 35.12(d) that establishes requirements for license applications for other medical uses of byproduct material as described in § 35.1000. Specifically, § 35.12(d) requires that, in addition to the information currently required in Form NRC–313, "Application for a Materials License," the applicant must also supply the following:

- Any information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of 10 CFR Part 35;
- Any specific information necessary for: (1) radiation safety precautions and instructions; (2) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (3) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.
- Any other information requested by the Commission in its review of the application.

Cost Impacts: NRC intends for this provision to allow applicants and licensees to submit license applications for medical uses not specifically addressed in Subparts D–H of the final rule. Thus, license applications for new or emerging technologies could be submitted under § 35.12(d) instead of requiring applicants or licensees to submit an exemption request under § 35.19. However, because of the nature of emerging technologies, all of the information needed for approval of such technologies cannot be specified in advance.

Cost savings may result for applicants or licensees from a reduction in time to prepare applications for new or emerging technologies not addressed in Subparts D–H compared to time necessary to seek approval via an exemption.

Assumptions:

Licensees: Total annual licensee applications: 2; Reduced application preparation time, hours: 4; Physician hourly rate[4] $100; Total Annual Cost Savings for licensees: $1,000[5]; Total Annual Cost Savings from amendment to § 35.12(d): $1,000.

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[4] The regulatory analysis assumes the following hourly rates, by labor category, fully loaded: RSO/Authorized User/Medical Physicist/Physician/Administrator/Management: $100; Scientific Staff: $50; Technical Staff: $30; Clerical Staff: $18.

[5] Costs below $500 rounded down; costs at or above $500 rounded up to nearest thousand.

Health and Safety Impacts: None anticipated.
Benefits: Cost savings to licensees.

5.10 License amendments (§ 35.13).

Section 35.13 currently specifies the circumstances under which a licensee must apply for and receive a license amendment.

Section 35.13(b) currently requires a licensee to obtain a license amendment before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, unless

- Under § 35.13(b)(1) the authorized user is certified by an organization specified in 10 CFR Part 35; or
- Under § 35.13(b)(2) the authorized nuclear pharmacist is certified by an organization specified in 10 CFR Part 35; or
- Under § 35.13(b)(3) the person is identified as an authorized user or authorized nuclear pharmacist on an NRC or Agreement States license; or
- Under § 35.13(b)(4) the person is identified as an authorized user or authorized nuclear pharmacist on a permit issued by an NRC or Agreement States specific licensee of broad scope.

Section 35.13(c) currently requires a licensee to obtain a license amendment before it changes Radiation Safety Officers or Teletherapy Physicists.

The final rule, in § 35.13(b), requires a licensee to obtain a license amendment before it permits anyone to work as an authorized nuclear pharmacist, authorized user, or authorized medical physicist, unless the individual meets specified conditions described in paragraphs (b)(1) through (b)(4).

The final rule, in § 35.13(c), continues to require a licensee to obtain a license amendment before it changes Radiation Safety Officers, except as provided in § 35.24(c). The final rule also amends § 35.13(e), which requires a licensee to obtain a license amendment before adding to or changing the areas of use. Specifically, § 35.13(e) of the final rule does not require licensees to submit a license amendment for changes of area of use for medical uses permitted under §§ 35.100 and 35.200.

Cost Impacts: NRC anticipates cost savings to licensees and NRC from a reduction in the number of license amendments that will be submitted to NRC to add teletherapy physicists (changed to medical physicists) to a license (§ 35.13(c)) and areas of use where byproduct material is used in accordance with §§ 35.100 or 35.200 (§ 35.13(e)).

Assumptions (§ 35.13(c)):

Licensees: License amendment applications[6] (20 percent of 60 licensees need to apply for one amendment/year)[7]: 12; Physician/management amendment preparation time, hours: 1; Physician/management hourly rate: $100; Technical staff hours to prepare amendment: 4; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $3,000.

NRC/Agreement States:[8]

Total amendments: 12; NRC/Agreement States amendment review time, hours: 4; NRC/Agreement States hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States: $4,000; Total Annual Cost Savings from amendment to § 35.13(c): $7,000.

NRC also anticipates cost savings to licensees and NRC or Agreement States from a reduction in the number of license amendments that will be submitted for changes in areas of use.

Assumptions (§ 35.13(e)):

Licensees: Total annual amendments for changes in areas of use: 510[9]; Physician amendment preparation time, hours: 1; Physician hourly rate: $100; Technical staff

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[6] The NRC license tracking system does not generate data on license amendments by type of action requested. In addition, one amendment application may include a request for several actions. The estimated number of amendment applications per year therefore may overstate the number of requests received. Estimates are based on discussions with NRC Regional Staff and State personnel on the regulatory working group.

[7] The labor turnover rate in the U.S. economy averages approximately 20 percent, as of March 2000. This rate may overstate slightly the turnover rate for medical physicists.

[8] NRC no longer charges a separate, per-amendment fee. The NRC has amended 10 CFR 170.31 to eliminate the flat amendment fee for materials licensees. (64 FR 31460; June 10, 1999). A labor rate of $75/hour is used for NRC labor costs, which represents a partially loaded blended rate of technical, clerical, and managerial staff. The $75/hour labor rate also is used for Agreement States labor costs.

[9] Assumes approximately 12.5 percent of all annual amendment requests involve changes in areas of use for §§ 35.100 and 35.200. Estimated based on Program Codes 2120, 2121, 2200, and 2201. See Footnote 3 to Table 2.

amendment preparation time, hours: 2; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $82,000.

NRC/Agreement States:

Total annual amendments for changes in areas of use: 510 [9]; NRC/Agreement States amendment review time, hours: 2; NRC/Agreement States hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States: $77,000; Total Annual Cost Savings for § 35.13(e): $159,000; Total Annual Cost Savings from § 35.13: $166,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings to licensees, NRC, and Agreement States.

5.11 Notifications (§ 35.14).

Section 35.14(a) currently requires licensees to provide the Commission with a copy of the board certification or the permit issued by a licensee of broad scope for each individual who is allowed to work as an authorized user or an authorized nuclear pharmacist. Section 35.14(b)(1) requires the licensee to notify the Commission by letter when an authorized user, authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change.

The final rule amends §§ 35.14(a) and (b)(1) to add authorized medical physicist to the list of persons about whom the licensee must notify the Commission while simultaneously deleting teletherapy physicist from the list. The final rule, in § 35.14(a), adds permits issued by a Commission master material license broad scope permittee. The final rule adds § 35.14(b)(3) to clarify the requirement concerning notice when the licensee's name changes; and adds § 35.14(b)(4) to require notification when the licensee has added to or changed the areas of use identified in the application or on the license and permitted under §§ 35.100 or 35.200.

Cost Impacts: NRC anticipates a small cost increase as a result of an increase in the number of notices that licensees will be required to submit. Of those licensees employing a medical physicist (estimated at about 617 licensees), about 20 percent are estimated to notify NRC or Agreement States agencies at least one additional time per year.

Assumptions (§ 35.14(b)(1)):

Licensees: NRC/Agreement States licensee notifications pertaining to medical physicists: 123; Annual licensee notification, hours: 0.5; Technical staff hourly rate: $30; Total Annual Cost Increase for licensees: $2,000.

NRC/Agreement States: NRC/Agreement States licensee notifications: 123; NRC/Agreement States review time: 0.25; NRC/Agreement States hourly rate: $75; Total Annual Cost Increase for NRC and Agreement States: $2,000; Total Annual Cost Increase for § 35.14(b)(1): $4,000.

NRC also anticipates a small cost increase as a result of requiring licensees to report changes in the area of use. However, NRC estimates only a small number of total annual applications will be due to changes in license area of use (12.5 percent of 4080 annual license notifications).

Assumptions (§ 35.14(b)(4)):

Licensees: Total annual notification of changes in licensee's areas of use: 510; Notification preparation time, hours: 0.5; Technical staff hourly rate: $30; Total Annual Cost Increase for licensees: $8,000.

NRC/Agreement States: Total annual notification of changes in licensee's areas of use: 510; NRC/Agreement States review time, hours: 0.25; NRC/Agreement States hourly rate: $75; Total Annual Cost Increase for NRC and Agreement States: $10,000; Total Annual Cost Increase for § 35.14(b)(4): $18,000; Total Annual Cost Increase for § 35.14: $22,000.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change with substitution of term "medical physicist" for "teletherapy physicist." Also, increased flexibility and reduced regulatory burden for licensees are anticipated.

5.12 Exemptions regarding Type A specific licenses of broad scope (§ 35.15).

Section 35.15(d) currently exempts a licensee possessing a Type A specific license of broad scope for medical use from the provisions of § 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.

The final rule amends §§ 35.15(a) and (b) to authorize the exemption of a licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33, from the provisions of § 35.12(d) regarding the need to file an amendment to the license for medical uses of byproduct material, as described in § 35.1000, and the provisions of § 35.13(b), respectively. Section 35.15(c) exempts a licensee with Type A specific license of broad scope for medical use from the provisions of

§ 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the application or on the license.

The final rule amends § 35.15(d) to exempt a licensee with Type A specific license of broad scope for medical use from the provisions of § 35.14(a).

The final rule adds new §§ 35.15(e)–(g) to exempt Type A license holders from the provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist; provisions of § 35.14(b)(4) regarding additions to or changes in the areas of use identified in the application or on the license where byproduct material is used in accordance with §§ 35.100 or 35.200; and the provisions of § 35.49(a).

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.13 License issuance (§ 35.18).

Section 35.18 currently specifies the requirements for license issuance for use of byproduct material. Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine services.

The final rule adds a new § 35.18(b) providing that the Commission will issue a license for mobile services if: (1) the applicant meets the requirements specified in § 35.18(a); and (2) assures that individuals or human research subjects to whom byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

Cost Impacts: No cost impacts are anticipated for licensees. Section 35.29 has been eliminated and replaced with requirements in final §§ 35.18(b) and 35.80. The final rule promulgates, in § 35.18(b), a criterion currently being implemented through licensing.

Health and Safety Impacts: None anticipated.

Benefits: If the amendment leads to an increase in the availability of mobile services, patients could experience benefits as a result of lessened travel to reach medical care.

5.14 Specific exemptions (§ 35.19).

Section 35.19 currently provides that the Commission may grant exemptions from the 10 CFR Part 35 requirements. It states that the Commission will review requests for exemptions from the training and experience requirements with the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

The final rule eliminates the reference to assistance from the ACMUI. NRC anticipates, however, that the Commission will continue to review such exemption requests with the assistance of ACMUI.

Cost Impacts: No cost impacts are anticipated because the only change is the elimination of the reference to assistance from the ACMUI.

Health and Safety Impacts: None anticipated.

Benefits: The current text regarding the ACMUI is a Commission policy position and is not a regulatory requirement. Therefore, this text was removed for improved clarity.

SUBPART B—GENERAL ADMINISTRATIVE REQUIREMENTS

5.15 ALARA program (§ 35.20).

Section 35.20 currently requires that licensees develop and implement a written radiation protection program that includes provisions for keeping doses as low as reasonably achievable (ALARA) and specifies program content and participants.

The final rule eliminates § 35.20.

Cost Impacts: None anticipated. NRC considers the requirements of 10 CFR Part 20, particularly 10 CFR 20.1101, to be commensurate with the scope and extent of 10 CFR Part 35 ALARA requirements. Specifically, 10 CFR 20.1101 requires licensees to develop, document, and implement a radiation protection program and includes ALARA requirements. This is comparable to 10 CFR Part 35, where licensees are required to develop an ALARA program for activities conducted under 10 CFR Part 35.

In the final rule, the current ALARA requirements in § 35.20 are unnecessary, given a performance-based approach, because ALARA is already required under 10 CFR 20.1101. However, no costs will be avoided in the final rule because licensees are still required by 10 CFR Part 20 to keep doses as low as reasonably achievable.

Health and Safety Impacts: None anticipated because 10 CFR Part 20 continues to require an ALARA program.

Benefits: Eliminates the prescriptive requirements in § 35.20 and provides licensees with greater flexibility regarding ALARA programs.

5.16 Radiation Safety Officer (§ 35.21).

Section 35.21 currently requires that each licensee appoint a Radiation Safety Officer (RSO).

Section 35.21(a) requires each licensee to appoint an RSO who is responsible for implementing the radiation safety program. The licensee, through the RSO, ensures compliance with the radiation safety program.

Section 35.21(b) specifies the duties and responsibilities of the RSO.

The final rule eliminates § 35.21 and replaces it in 10 CFR Part 35 with § 35.24, which addresses the authority and responsibilities for the radiation protection program, including specific requirements regarding the RSOs.

Cost Impacts: Cost impacts are evaluated under § 35.24.

Health and Safety Impacts: No health and safety impacts are anticipated from elimination of § 35.21 because § 35.24 specifically addresses requirements regarding the RSO.

Benefits: Conforming change to restructuring of 10 CFR Part 35 to be more performance-based.

5.17 Elimination of § 35.22 of the Current Rule (Radiation Safety Committee).

Section 35.22 currently requires that each medical institution licensee establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. Section 35.22(a) specifies the required membership of the RSC, meeting frequency, criteria for a quorum, content of minutes, distribution of minutes and the required retention period of minutes. Section 35.32(b) requires the RSC to perform specific reviews.

The final rule eliminates § 35.22, and replaces it with a new § 35.24, which addresses the authority and responsibilities for the radiation protection program, including a requirement (§ 35.24(f)) that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H must establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members whom the licensee considers appropriate.

Cost Impacts: The elimination of § 35.22 results in significant cost savings for certain categories of licensees because of the deletion of the requirement to hold quarterly Radiation Safety Committee meetings. The impacts of the elimination of § 35.22 and its replacement by § 35.24 are described under § 35.24.

Health and Safety Impacts: No health and safety impacts are anticipated from elimination of § 35.22 because § 35.24 incorporates requirements for coordination of the radiation safety program.

Benefits: Significant cost savings to licensees as well as greater flexibility to licensees in coordinating radiation safety activities.

5.18 Statements of authority and responsibility (§ 35.23).

Section 35.23(a) currently requires that each licensee provide Radiation Safety Officers and Radiation Safety Committees sufficient authority to fulfill their duties and responsibilities. Section 35.23(b) requires the licensee to establish those authorities, duties, and responsibilities in writing and to retain the current edition as a record until the Commission terminates the license.

The final rule eliminates § 35.23, and replaces it with a new section, § 35.24, which specifies requirements for the radiation protection program, including written authorities, duties, and responsibilities of the RSO (§ 35.24(e)).

Cost Impacts: Cost impacts are evaluated under § 35.24.

Health and Safety Impacts: No health and safety impacts are anticipated from elimination of § 35.23, because § 35.24 incorporates requirements for written statements of authorities, duties, and responsibilities of the RSO.

Benefits: Conforming change to restructuring of 10 CFR Part 35 to be more performance-based.

5.19 Authority and responsibilities for the radiation protection program (§ 35.24).

The final rule contains a new section, § 35.24, specifying authority and responsibility for the radiation protection program.

Section 35.24(a) provides that, in addition to the radiation protection program requirements of 10 CFR 20.1101, a licensee's management must approve: (1) requests for license application, renewal, or amendment before submittal; (2) any individual, before allowing that individual to work as an authorized user, authorized nuclear

pharmacist, or authorized medical physicist; and (3) radiation protection program changes that do not require a license amendment and are permitted under § 35.26.

Section 35.24(b) requires a licensee's management to appoint an RSO who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that the licensee's radiation safety activities are being performed in accordance with the licensee-approved procedures and regulatory requirements.

Section 35.24(c) authorizes a licensee to permit, for up to 60 days each year, an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in § 35.24(g), if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of § 35.24.

Section 35.24(d) allows a licensee to simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c), if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different uses of byproduct material permitted by the license.

Section 35.24(e) requires licensees to establish in writing the authority, duty, and responsibilities of the RSO.

Section 35.24(f) requires licensees that are authorized for two or more types of byproduct material under Subparts E, F, and H or two or more units under Subpart H, to establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members whom the licensee considers appropriate.

Section 35.24(g) requires licensees to provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to fulfill their duties to identify radiation safety problems; initiate, recommend, or provide corrective actions; stop unsafe operations; and verify implementation of corrective actions.

Section 35.24(h) requires recordkeeping under paragraphs (a), (b) and (e) in accordance with new § 35.2024.

Cost Impacts: No cost impacts are anticipated from § 35.24(a), because licensees continue to be allowed to make changes to their radiation protection program, as currently allowed by § 35.31.

Minimal cost impacts are anticipated from the requirement in § 35.24(b) that the RSO must agree in writing to perform the duties of RSO. The RSO is required to perform a prescriptive list of duties in the current rule, § 35.21. This change will allow greater flexibility.

Minimal cost savings are anticipated from the provisions in § 35.24(c) and (d) that a licensee may appoint multiple temporary RSOs. Greater flexibility will be provided to licensees.

There are no cost impacts from the requirement in § 35.24(e) that a licensee establish the authority, duties, and responsibilities of the RSO in writing because this requirement is carried over from the current rule, § 35.23.

Cost savings to licensees are anticipated from the provision in § 35.24(f) that only licensees that are licensed for two or more different uses of byproduct material under Subparts E, F, and H or two or more types of units under Subpart H must establish a Radiation Safety Committee. Licensees under Subparts D and G that use only unsealed byproduct material for which a written directive is not required are not required to have a Radiation Safety Committee. In addition, § 35.24(f) eliminates prescriptive requirements in §§ 35.22(a)(2) and (3) of the current rule requiring meetings to be held at least quarterly, specifying what constitutes a quorum, specifying the contents of minutes, and specifying in detail the required activities of the Radiation Safety Committee.

NRC estimates that about 20 percent of medical institutions will not be required to have Radiation Safety Committees. In addition, NRC estimates that the costs of Radiation Safety Committees to those licensees that are required to maintain them will be reduced by 10 percent under the final rule.

The costs associated with § 35.24(f) are estimated as follows:

Assumptions:

Licensees not required to set up RSCs: Total licensee meetings eliminated annually: 3,010; Persons responsible for coordination: 4; Time saved per meeting eliminated, hours: 2; Combined staff hourly rate (medical, scientific, technical): $75; Total Annual Cost Savings from meetings eliminated by § 35.24(f): $1,806,000.

Licensees required to set up RSCs: Total licensee meetings annually: 12,040; Persons responsible for coordination: 4; Reduced time required per meeting, hours: 0.1;

Combined staff hourly rate (medical, scientific, technical): $75; Total Annual Cost Savings from reduced requirements under § 35.24(f): $361,000; Total Annual Cost Savings from elimination of § 35.22 by § 35.24(f): $2,167,000.

No cost impacts are anticipated from the new §§ 35.24(c), (d), and (e), because they continue to specify duties and responsibilities of Radiation Safety Officers.

Health and Safety Impacts: No health and safety impacts are anticipated from the new §§ 35.24(c), (d), and (e) because they continue to specify duties and responsibilities of Radiation Safety Officers. No health or safety impacts are anticipated under § 35.24(f) because Subpart E, F, and H licensees continue to be required to have Radiation Safety Committees.

Benefits: Provides greater flexibility to licensees.

5.20 Radiation protection program changes (§ 35.26).

Section 35.31(a) currently allows licensees to make minor changes to their radiation safety procedures that do not impact safety, and lists examples of such changes. Section 35.31(b) requires records of such changes to be kept until the license is renewed or terminated, and specifies that changes must be signed by the Radiation Safety Officer, the affected authorized user(s), and the licensee's management or in medical institutions, the chairman of the Radiation Safety Committee and the management representative.

The final rule renumbers § 35.31 as § 35.26 and makes the following changes:

Section 35.26(a) allows licensees to revise their radiation protection program without Commission approval, provided the change: (1) does not require an amendment under § 35.13; (2) is in compliance with the regulations and the license; and (3) has been reviewed and approved by the RSO and licensee management, and provided that affected individuals are instructed on the revised program before the changes are implemented. Also, § 35.26(a) eliminates the examples of ministerial changes previously listed in § 35.31(a).

Section 35.26(b) requires the licensee to maintain a record of each change in accordance with § 35.2026.

Cost Impacts: On balance, cost savings are anticipated from the final rule.

Assumptions:

Licensees: Total licensees: 5,793; Net reduction in time, hours: 0.08; Technical staff hourly rate: $30; Total Annual Cost Savings from § 35.26: $14,000.

Health and Safety Impacts: No health and safety impacts are anticipated from the changes to § 35.26.

Benefits: Cost savings to licensees.

5.21 Supervision (§ 35.27).

Section 35.25(a) currently requires that each licensee permitting an individual to use byproduct material under the supervision of an authorized user must: (1) instruct the supervised individual in radiation safety and the licensee's written quality management program; (2) require the supervised individual to follow the instructions of the authorized user, follow radiation safety and quality management procedures and comply with regulations and license conditions; and (3) periodically review the supervised individual's use of byproduct material and records kept to reflect that use.

Section 35.25(b) currently requires that each licensee permitting preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or a physician who is an authorized user, must: (1) instruct the supervised individual in preparation of byproduct material for medical use, radiation safety, and the licensee's quality management program; (2) require the supervised individual to follow certain instructions, and to comply with the regulations and license conditions; and (3) periodically review the work of the supervised individual and the records kept to reflect that work.

The final rule renumbers § 35.25 as § 35.27 and makes the following changes:

Section 35.27(a) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by § 35.11(b)(1), in addition to the requirements in § 19.12, to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and to require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations, and license conditions with respect to the medical use of byproduct material. The final rule deletes references to the licensee's quality management program. The final rule eliminates the requirement to instruct the supervised individual in the licensee's written qual-

ity management program and to periodically review the supervised individual's use of byproduct material and records.

Section 35.27(b) requires a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2) in addition to the requirements in § 19.12, to instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and to require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures established by the licensee and the regulations of this chapter, and license conditions. The final rule eliminates the requirement to instruct the supervised individual in the licensee's written quality management program and to periodically review the individual's work as it pertains to preparing byproduct material for medical use and records kept to reflect that work.

Section 35.27(c) requires that a licensee that permits supervised activities under §§ 35.27 (a) and (b) be responsible for the acts and omissions of the supervised individual.

Cost Impacts: Increased costs are anticipated by requiring licensees to instruct the supervised individual on the regulations and license conditions.

Assumptions:

Licensees: Total NRC/Agreement States licensees: 5,793; Authorized user instruction time, hours: 2; Authorized user hourly rate: $100; Total Cost Increase for § 35.27(a)(1): $1,159,000.

Decreased costs are anticipated by § 35.27(b) no longer requiring licensees to conduct periodic reviews of supervised individuals' work and records.

Assumptions (elimination of periodic reviews):

Licensees: Total NRC/Agreement States licensees: 5,793; Authorized user periodic review time (quarterly reviews), hours: 4; Authorized user hourly rate: $100; Total Annual Cost Savings for § 35.27(b): $2,317,000; Total Annual Cost Savings from § 35.27: $1,158,000.

Health and Safety Impacts: Increased radiation safety.

Benefits: Cost savings and increased flexibility for licensees.

5.22 Administrative requirements that apply to the provision of mobile nuclear medicine service (§ 35.29).

Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine service licensees.

The final rule eliminates § 35.29, and replaces it with requirements in final §§ 35.18(b) and 35.80.

Cost Impacts: Cost impacts are addressed under §§ 35.18(b) and 35.80 of the final rule.

Health and Safety Impacts: No health and safety impacts are anticipated from elimination of § 35.29 because administrative requirements for mobile nuclear medicine services continue to be addressed under the final §§ 35.18(b) and 35.80.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

5.23 Quality Management Program (§ 35.32).

Section 35.32 currently requires each licensee to establish and maintain a written quality management program (QMP).

Section 35.32(a) requires that the quality management program must include procedures for preparing written directives for teletherapy, gamma stereotactic radiosurgery, brachytherapy, administrations of sodium iodide I–125 or I–131 in quantities greater than 30 microcuries, and therapeutic administrations of a radiopharmaceutical other than sodium iodide I–125 or I–131; verifying the patient's identity by more than one method; ensuring that each administration is in accordance with the written directive and any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

Section 35.32(b) requires that the licensee must develop procedures for and conduct a review of the quality management program at least annually.

Section 35.32(c) requires evaluation and response to each recordable event.

Section 35.32(d) provides for retention of specified records.

Section 35.32(e) permits licensees to make certain modifications to the quality management program. These changes are required to be submitted to the NRC.

Section 35.32(f) requires each applicant for a new license to submit a quality management program.

The final rule eliminates § 35.32. The final regulations in §§ 35.40 and 35.41 establish requirements for written directives and procedures to be followed for admin-

istrations requiring a written directive. This change results in significant cost saving to medical use licensees as compared to the current § 35.32.

Cost Impacts: The deletion of § 35.32 results in significant cost savings.

Assumptions (elimination of § 35.32(b)):

Licensees: Total affected licensees: 3,165; Hours for annual licensee QMP review/recordkeeping: 14; Authorized user hourly rate: $100; Total Annual Cost Savings for licensees: $4,431,000.

NRC/Agreement States (elimination of § 35.32(f)): NRC/Agreement States review of each licensee's QMP review: 8; NRC/Agreement States staff hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States: $1,899,000.

Each applicable licensee is currently required by § 35.32(c) to evaluate and respond to each recordable event, including retaining records of the event for 3 years. The analysis assumes 80 annual events for which technical staff address the provisions of § 35.32(c).

Assumptions (elimination of § 35.32(c)):

Licensees: Annual number of recordable events: 80; Licensee response time, hours: 2; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $5,000; Total Annual Cost Savings from elimination of § 35.32(c) for licensees and NRC and Agreement States: $6,335,000.

Health and Safety Impacts: No health and safety impacts are anticipated from elimination of § 35.32 because § 35.40 retains requirements for written directives and § 35.41 retains requirements for procedures requiring a written directive.

Benefits: Cost savings to licensees.

5.24 Notifications, reports, and records of misadministrations (§ 35.33).

Section 35.33 currently requires that each licensee notify NRC, by phone, no later than the next calendar day, when a "misadministration" occurs; notify the referring physician and also notify the individual receiving the misadministration within 24 hours (unless the referring physician personally informs the licensee that he will inform the individual or that, based on medical judgment, telling the individual be harmful); and submit a written report to NRC and the individual notified within 15 days. Section 35.33 requires records of misadministrations to be retained for 5 years.

The final rule eliminates § 35.33. Requirements for reporting "medical events" are established by the final rule under § 35.3045. Section 35.2 defines "medical event" as an event that meets the criteria of § 35.3045(a). Section 35.3045(a) of the final rule, a new section, revises the requirements in § 35.33 of the current rule. Section 35.3045(a) replaces the word "misadministration" with "medical event" and makes other changes defining the situations in which reports must be made. However, the changes in § 35.3045 are not expected to change the number or type of medical events that are reported under § 35.3045 substantially from the number and type of misadministrations reported under the current rule.

Cost Impacts: Cost impacts are evaluated under § 35.3045.

Health and Safety Impacts: No health and safety impacts are anticipated from elimination of § 35.33 because § 35.3045 essentially maintains reporting requirements for medical events.

Benefits: Conforming change to restructuring of 10 CFR Part 35 to be more performance-based.

5.25 Written directives (§ 35.40).

The final rule adds a new § 35.40(a) providing that a written directive must be dated and signed by the authorized user before the administration of I–131 sodium iodide greater than 1.11 Megabequerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material.

Section 35.40(b) specifies that the written directive must contain the name of the patient or human research subject and the following information: for any administration of quantities greater than 1.11 MBq of sodium iodide I–131: the dosage; for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I–131: the radioactive drug, dosage, and route of administration; for gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site; for teletherapy: the total dose, dose per fraction, number of fractions, and treatment site; for high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; and for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders: before implantation: treatment site, the radionuclide, and dose, and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Section 35.40(c) provides that a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

Section 35.40(d) specifies that the licensee must retain the written directive in accordance with § 35.2040 of the final rule.

Cost Impacts: No costs are either avoided or increased for licensees, Agreement States, or NRC because § 35.40 essentially retains the requirements in the current § 35.32(a) regarding written directives.

Health and Safety Impacts: None anticipated.

Benefits: Reduced regulatory burden to licensees compared to the current § 35.32 Quality Management Program, while maintaining an adequate level of health and safety.

5.26 Procedures for administrations requiring a written directive (§ 35.41).

The final rule adds a new § 35.41. Section 35.41(a) requires for any administration requiring a written directive that the licensee must develop, implement, and maintain written procedures to provide high confidence that before each administration the patient's identity is verified and that each administration is in accordance with the written directive. Section 35.41(b) specifies that the contents of the procedures must include: (1) verifying the identity of the patient or human research subject; (2) verifying that the administration is in accordance with the treatment plan, if applicable, and written directive; (3) checking both manual and computer-generated dose calculations; and (4) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600. Section 35.41(c) requires that a licensee retain a copy of the procedures required under § 35.41(a) in accordance with § 35.2041.

Cost Impacts: No costs are either avoided or increased for licensees, Agreement States, or NRC because the current § 35.32(a) requires licensees to have procedures in place to provide high confidence that administrations of byproduct material or radiation from byproduct material are as directed by the authorized user. The cost avoided by eliminating reviews and recordkeeping associated with these procedures is addressed under § 35.32.

Health and Safety: None anticipated.

Benefits: Reduced regulatory burden to licensees compared to the current § 35.32 Quality Management Program (i.e., flexibility in program management), while maintaining an adequate level of health and safety.

5.27 Suppliers for sealed sources or devices for medical use (§ 35.49).

Section 35.49 currently provides that a licensee may use for medical use only: (a) sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and § 32.74 or the equivalent requirements of an Agreement State; or (b) teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or the equivalent requirements of an Agreement State.

The final rule amends the text of § 35.49 to provide that for medical use, a licensee also may use sealed sources or devices noncommercially transferred from a Part 35 licensee.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Greater clarity concerning the sealed sources and devices that may be used for medical uses.

5.28 Training for Radiation Safety Officer (§ 35.50).

The current rule, in § 35.900, specifies the training requirements for a Radiation Safety Officer.

Section 35.900(a) lists nine specialist boards through which an individual may become certified to be an RSO.

Alternatively, § 35.900(b) specifies training and experience requirements that may be met in lieu of certification by one of the nine listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 1 year of full time experience as a radiation safety technologist at a medical institution under the supervision of the RSO.

Alternatively, § 35.900(c) allows an individual to be the Radiation Safety Officer if the individual is an authorized user identified on the licensee's license.

The final rule renumbers § 35.900 as § 35.50 and makes the following changes:

The list of nine approved speciality boards is eliminated. Section 35.50(a) provides instead that the licensee shall require an individual fulfilling the responsibilities of the RSO to be certified by a speciality board whose certification process includes all of the requirements in § 35.50(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, under § 35.50(b) the individual is required to have completed: (1) a structured educational program consisting of 200 hours of didactic training in specified areas; and (2) 1 year of full time radiation safety experience under the supervision of an individual identified as the RSO on a Commission or Agreement State license that authorizes similar types of use(s) of byproduct material involving specified experience. Also, the individual must obtain written certification, signed by a preceptor RSO, that the individual has completed the required training and the individual has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license.

Alternatively, under § 35.50(c), the individual is required to be an authorized user, an authorized medical physicist or authorized nuclear pharmacist identified on the licensee's license and to have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.

Cost Impacts: The cost impacts associated with this section involve additional costs to NRC/Agreement States for recognition of certifying specialty boards, to certifying boards for preparing materials supporting their recognition, and to some licensees and individuals seeking to be an RSO for the cost of preceptor certification. NRC estimates that approximately 190 individuals will seek to become Radiation Safety Officers under § 35.50 annually. Of these, 90 percent, or 171, will seek certification by a certifying board under § 35.50(a). No additional cost impacts be created for them under the final rule. NRC estimates that the remainder, or approximately 19 individuals, will seek to become Radiation Safety Officers under § 35.50(b). New costs for securing a preceptor statement are created by the final rule.

Under § 35.50(a), NRC/Agreement States incur costs for recognizing specialty boards for purposes of § 35.50(a). NRC estimates that recognition by NRC/Agreement States of specialty boards for certification requires four hours per board and that NRC/Agreement States will be required to review five boards for approval.[10]

Assumptions:

NRC/Agreement States: Number of boards reviewed: 5; NRC/Agreement States review time: 4 hours/board at $75 per hour; Total Cost Increase: $2,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards seeking recognition: 5; Preparation of submission:12 hours/board for Technical Staff at $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $4,000; Total Cost Increase for § 35.50(a): $6,000.

Under § 35.50(b), licensees and preceptors incur costs associated with securing a preceptor's certification for purposes of § 35.50(b).

Assumptions:

Licensees: Number of candidates: 19; Cost of preceptor certification: ½ hour at $20 hour for candidate[11] plus ½ hour at $100/hour for preceptor; Total Cost Increase for § 35.50(b): $1,000; Total Cost Increase for § 35.50: $7,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.29 Training for authorized medical physicist (§ 35.51).

The current rule, in § 35.961, specifies the training requirements for a teletherapy physicist.

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[10] NRC will allow medical certifying boards to submit one application for recognition that addresses every training and experience section of the final rule for which they believe the board's diplomates should be deemed to meet the requirements. However, the number of boards that are estimated to seek recognition under each training and experience section in this analysis reflects the assumption that while some boards will submit one application for multiple sections, boards also may choose to prepare more that one application when the training and experience requirements for the different sections for which they are applying are significantly different.

[11] Candidate's time measured at $20 per hour based on an individual's estimated annual salary of $30,000 to $40,000.

Section 35.961(a) and (b) each list one specialist board through which an individual may become certified.

Alternatively, § 35.961(c) specifies training and experience requirements that may be met in lieu of certification by one of the listed speciality boards. It currently requires holding a master's or doctor's degree in one of four areas. In addition, 1 year of full time training in therapeutic radiological physics followed by 1 year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes performing specified tasks is required.

The final rule renumbers § 35.961 as § 35.51, changes "teletherapy physicist" to "authorized medical physicist," and makes the following additional changes:

The list of two approved speciality boards is eliminated. Section 35.51(a) provides that the licensee shall require the authorized medical physicist to be an individual who is certified by a specialty board whose certification process includes all of the training and experience requirements in § 35.51(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.51(b)(1) adds "medical physics" to the list of degrees approved by NRC. Section 35.51(b)(1) continues to require 1 year of full time training in therapeutic radiological physics followed by 1 year of full time work experience but adds to the list of specified tasks that must be performed under supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in § 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable.

Section 35.51(b)(2) adds a requirement that the candidate medical physicist must obtain written certification, signed by a preceptor authorized medical physicist, that the training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an authorized medical physicist.

Cost Impacts: The cost impacts associated with this section involve additional costs to NRC/Agreement States to recognize certifying specialty boards, to certification boards for preparing materials supporting their recognition, and to some licensees and individuals seeking to be an authorized medical physicist for the cost of preceptor certification.

NRC estimates that approximately 100 physicists will seek to become authorized medical physicists under § 35.51 or equivalent Agreement State regulations annually. Of these, 90 percent, or 90, will seek certification by a certifying board under § 35.51(a). No additional cost impacts will be created for them under the final rule. NRC estimates that the remainder, or approximately 10 physicists, will seek to become authorized medical physicists under § 35.51(b). New costs for securing a preceptor statement are created by the final rule.

NRC estimates that approval by NRC/Agreement States of specialty boards for certification for purposes of § 35.51(a) will require four hours per board and that NRC/Agreement States will be required to review two boards for recognition. The costs to NRC/Agreement States for certifying specialty boards are estimated below.

Assumptions:

NRC/Agreement States: Number of boards reviewed: 2; NRC/Agreement States review time: 4 hours/board at $75 per hour; Total Cost Increase: $1,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards reviewed: 2; Preparation of submission: 12 hours/board for Technical Staff at $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $2,000; Total Cost Increase for § 35.51(a): $3,000.

The costs to licensees and preceptors associated with securing a preceptor's certification for purposes of § 35.51(b) are estimated below.

Assumptions:

Licensees: Number of candidates: 10; Cost of preceptor certification: ½ hour at $20/hour for candidate plus ½ hour at $100/hour for preceptor; Total Cost Increase for § 35.51(b): <$1,000; Total Cost Increase for § 35.51: $3,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.30 Training for an authorized nuclear pharmacist (§ 35.55).

The current rule, in § 35.980, specifies the training requirements for an authorized nuclear pharmacist.

Section 35.980(a) lists one specialist board through which an individual may become certified to perform these procedures.

Alternatively, § 35.980(b)(1) specifies training and experience requirements that may be met in lieu of certification by the listed speciality board. It currently requires 700 hours of classroom and laboratory training in specified subjects as well as supervised experience in specified tasks.

Section 35.980(b)(2) requires that the candidate pharmacist must obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the training has been completed and the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

The final rule renumbers § 35.980 as § 35.55 and makes the following changes:

The listing of approved speciality boards is eliminated. Section 35.55(a) provides instead that the licensee shall require the authorized nuclear pharmacist to be a pharmacist who is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in § 35.55(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.55(b) requires: (1) the pharmacist to have completed 700 hours in a structured educational program consisting of both didactic training in specified subjects and supervised practical experience in a nuclear pharmacy performing specified tasks; and (2) to have obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the didactic training and supervised practical experience and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Cost Impacts: The cost impacts associated with this section involve additional costs to NRC/Agreement States to recognize specialty boards, to certification boards for preparing materials supporting their recognition, and to some individuals seeking to be an authorized nuclear pharmacist for the cost of a preceptor certification.

NRC estimates that approximately 20 pharmacists will seek to become authorized nuclear pharmacists under § 35.55 or equivalent Agreement State regulations annually. Of these, 90 percent, or 19 pharmacists, will seek certification by a certifying board under § 35.55(a). No additional cost impacts are created for them under the final rule. NRC estimates that the remainder, or approximately one pharmacist, will seek to become an authorized nuclear pharmacist under § 35.55(b). New costs for securing a preceptor statement are created by the final rule.

Under § 35.55(a), NRC estimates that approval by NRC/Agreement States of specialty boards for certification will require four hours per board and that NRC/Agreement States will be required to review two boards for approval.

Assumptions:

NRC/Agreement States: Number of boards reviewed: 2; NRC/Agreement States review time: 4 hours/board at $75 per hour; Total Cost Increase: $1,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards reviewed: 2; Preparation of submission: 12 hours/board for Technical Staff at $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $2,000; Total Cost Increase for § 35.55(a): $3,000.

Under § 35.55(b), the costs to licensees associated with obtaining a preceptor's certification are estimated below.

Assumptions:

Licensees: Number of candidates: 1; Cost of preceptor certification: ½ hour at $20/hour for candidate plus ½ hour at $100/hour for preceptor; Total Cost Increase for § 35.55(b): <$1,000; Total Cost Increase for § 35.55: $3,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.31 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist (§ 35.57).

Three sections of the current rule, §§ 35.901, 35.970, and 35.981, address training requirements for experienced Radiation Safety Officers, experienced authorized users, and experienced nuclear pharmacists. (The current § 35.57 addresses authorization for calibration and reference sources. That topic is addressed in the final rule in § 35.65.)

The current rule, in § 35.901, provides that an individual identified as a Radiation Safety Officer on Commission or Agreement States license before October 1, 1986, need not comply with § 35.900.

The current rule, in § 35.970, provides that physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on Commission or Agreement States licenses before April 1, 1987, per-

forming only those methods of use for which they were originally licensed, need not comply with the training requirements and Subpart J.

The current rule, in § 35.981, requires licensees to apply for and receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before the individual can begin work as an authorized nuclear pharmacist. It allows pharmacists who completed a structured educational program, as specified in § 35.980(b)(1) before December 2, 1994, to qualify as an "experienced nuclear pharmacist" and need not comply with the requirements for a preceptor statement (§ 35.980(b)(2)) or recentness of training (§ 35.972).

The final rule renumbers and merges §§ 35.901, 35.970, and 35.981 as § 35.57 and makes the following changes:

Section 35.57(a) provides that an individual identified as a Radiation Safety Officer, teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license, or master material license permit or by a master material license permittee of broad scope, before a specified date, need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.

Section 35.57(b) replaces the April 1, 1987, threshold date associated with physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material with a date to be later specified. It also changes the training and experience citation from Subpart J to Subparts D through H.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

5.32 Recentness of training (§ 35.59).

The current rule, in § 35.972, specifies that the training and experience required under 10 CFR Part 35 must have been obtained within the 7 years preceding the application date or been met by continuing education and experience. (The current § 35.59 addresses requirements for possession of sealed sources and brachytherapy sources. That topic is addressed in the final rule in § 35.67.)

The final rule renumbers § 35.972 as § 35.59 and substitutes references to the appropriate Subparts B and D through H of the final rule for the citations to the training and experience requirements in the current rule.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

SUBPART C—GENERAL TECHNICAL REQUIREMENTS

5.33 Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material (§ 35.60).

Section 35.50 of the current rule requires licensees to possess a dose calibrator and to check each dose calibrator for constancy and to test each dose calibrator for accuracy, linearity, and geometric dependence. It specifies when these checks and tests must occur, and how they are performed.

The final rule combines requirements for calibration of instruments used to measure the activity of unsealed byproduct materials into one section, and renumbers § 35.50 as § 35.60. Section 35.60(a) requires, for direct measurements performed in accordance with § 35.63, that licensees possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. Section 35.60(b) requires a licensee to calibrate the instrumentation in accordance with nationally recognized standards or the manufacturer's instructions. Section 3560(c) requires a record of each instrument calibration to be retained in accordance with § 35.2060.

Cost Impacts: Cost savings are anticipated as a result of the requirements for instrument calibration becoming more flexible, more adaptable to new technology, and more performance-based. In addition, if a licensee administers only unit dosages from manufacturers or preparers and uses decay methods to determine the dosages, the licensee is not required to have a measurement instrument and, thus, is exempt from the calibration requirements of this section.

Assumptions:

Licensees: Total licensees: 5,793; Reduced annual testing, hours: 3; Technical staff hourly rate: $30; Total Annual Cost Savings from § 35.60: $521,000.

Health and Safety Impacts: No health and safety impacts are anticipated from this amendment.

Benefits: Cost savings to licensees who use only unit doses from manufacturers and preparers and use decay methods to determine the dosages and therefore are

not required to calibrate a measurement instrument, and cost savings to all licensees from increased flexibility in requirements for instrument calibration.

5.34 Calibration of survey instruments (§ 35.61).

Section 35.51 currently requires licensees to calibrate each survey instrument before first use, annually, and following repair. The current rule also requires the licensee to check each survey instrument for proper operation with a dedicated check source each day of use.

The final rule renumbers § 35.51 as § 35.61 and makes the following changes:

The final rule, in § 35.61(a), requires licensees to calibrate the survey instruments used to show compliance with 10 CFR Part 35 and with 10 CFR Part 20 before first use, annually, and following repairs that affect the calibration.

The final rule, in § 35.61(a), specifies that the licensee must calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source, calibrate two separated readings on each scale or decade that will be used to show compliance, and conspicuously note on the instrument the date of calibration.

Section 35.61(b) provides that the licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

The final rule eliminates the requirement that the survey instrument be checked for proper operation with a dedicated check source each day of use.

Section 35.61(c) requires the licensee to retain a record of each survey instrument calibration in accordance with § 35.2061.

Cost Impacts: Cost savings are anticipated for licensees from the elimination of daily checks with a dedicated check source.

Assumptions:

Licensees: Total licensees: 5,793; Annual days survey instruments checked: 260; Time to test survey instruments daily, hours: 0.003; Technical staff hourly rate: $30; Total Annual Cost Savings from § 35.61: $136,000.

Health and Safety Impacts: None anticipated. Under 10 CFR 20.1501(b), licensees continue to be required to ensure that instruments and equipment are calibrated periodically.

Benefits: Cost savings to licensees.

5.35 Determination of dosages of unsealed byproduct material for medical use (§ 35.63).

Section 35.53 currently requires that licensees measure the activity of dosages of unsealed byproduct material for medical use. It requires activity of dosages of a photon-emitting radionuclide to be measured, and activity of dosages of alpha- and beta-emitting radionuclides to be measured by direct measurement or a combination of measurements and calculations, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements. Results are required to be kept for 3 years and § 35.53 includes requirements for the contents of these records.

The final rule renumbers § 35.53 as § 35.63. Section 35.63(a) requires licensees to determine and record the activity of each dosage before medical use.

Section 35.63(b) provides that for a unit dosage this determination must be made by direct measurement of radioactivity or a decay correction, based on the activity or activity concentration determined by a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or an NRC or Agreement State licensee in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research.

Section 35.63(c) requires that for other than unit dosages, this determination must be made by direct measurement of radioactivity, a combination of measurement of radioactivity and mathematical calculations, or by a combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements.

Section 35.63(e) provides that the licensee must retain a record of the dosage determination in accordance with new § 35.2063.

Cost Impacts: The time necessary to perform a decay correction to determine the dosage of a unit dosage that is not measured directly is not significant different from the time necessary to remeasure a unit dosage in a dose calibrator. Cost savings result only for licensees who use only unit dosages, because they will not have to possess, use, and maintain a dose calibrator. However, most licensees are expected to retain possession of existing dose calibrators for use if needed.

Health and Safety Impacts: No health and safety impacts are anticipated from the changes to § 35.63 because unit dosages will be measured by the manufacturer or commercial nuclear pharmacy.

Benefits: NRC anticipates that licensees using only unit dosages will gain added flexibility under § 35.63 to rely on decay correction rather than direct measurement to determine the activity of dosages. If those licensees who use only unit dosages have no other need for a dose calibrator, they will not be required to obtain or replace dose calibrators for measurement of dosages.

Cost savings to licensees who use only unit dosages and do not possess a dose calibrator.

5.36 Authorization for calibration, transmission, and reference sources (§ 35.65).

Section 35.57 currently allows each authorized licensee to receive, possess, and use byproduct material for check, calibration, and reference use under specific requirements.

The final rule renumbers § 35.57 as § 35.65 and allows any person authorized by § 35.11 for medical use of byproduct material to receive, possess, and use any of the byproduct material specified in § 35.65 for check, calibration, transmission, and reference use as specified in §§ 35.65(a)–(d).

Section 35.65(a) specifies sealed sources manufactured and distributed by a person licensed under § § 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 Gbq (30 mCi) each. The final rule increases the maximum sealed source activity from 0.56 MBq (15 mCi) to 1.11 MBq (30 mCi).

Section 35.65(b) specifies sealed sources redistributed by a person licensed under §§ 32.74 or equivalent Agreement State regulations and that do not exceed 1.11 Gbq (30 mCi) each. The final rule specifies these redistributed sealed sources must be in the original packaging and shielding and be accompanied by the manufacturer's approved instructions. The final rule also increases the maximum sealed source activity from 0.56 MBq (15 mCi) to 1.11 MBq (30 mCi).

Section 35.65(c) specifies any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 Gbq (15 mCi).

Section 35.65(d) specifies any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 μCi) or 1,000 times the quantities in Appendix B of 10 CFR Part 30.

Section 35.65(e) specifies technicium–99m may be received, possessed, and used in amounts "as needed," rather than in amounts not to exceed 50 millicuries, as provided in the current rule.

Cost Impacts: Cost savings are anticipated with the final changes to § 35.65, formerly § 35.57. Licensees will not need to obtain license amendments to obtain higher activity check sources. NRC estimates that up to 151 amendments per year will be avoided.

Assumptions:

Licensees: Total NRC/Agreement States amendments avoided (estimated): 151; Technical staff preparation time, hours: 1; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $5,000.

NRC/Agreement States: NRC/Agreement States amendments avoided: 151; NRC/Agreement States amendment review: 1 hour/amendment at $75; Total Annual Cost Savings for NRC and Agreement States: $11,000; Total Annual Cost Savings from § 35.65: $16,000.

Health and Safety Impacts: None anticipated.

Benefits: Improved flexibility for licensees.

5.37 Requirements for possession of sealed sources and brachytherapy sources (§ 35.67).

Section 35.59 currently requires each licensee in possession of sealed or brachytherapy sources to follow the radiation safety and handling instructions supplied by the manufacturer as well as leak test requirements specified in § 35.59.

The final rule renumbers § 35.59 as § 35.67.

Section 35.67(a) requires licensees in possession of any sealed or brachytherapy source to follow the radiation safety and handling instructions supplied by manufacturers.

Section 35.67(b) requires a licensee in possession of a sealed source to test the source for leakage before its first use, unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

Section 35.67(c) requires that to satisfy leak test requirements, licensees must measure the sample so that the leak test can detect the presence of 185 Bq (0.005 Ci) of radioactive material in the sample.

Section 35.67(d) requires licensees to retain leak test records in accordance with § 35.2067.

Section 35.67(e) specifies that if the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination the licensee shall immediately withdraw the source from use and store, dispose, or cause it to be repaired in accordance with 10 CFR Parts 20 and 30. The licensee also is required to file a report within five days of the leak test in accordance with § 35.3067.

Section 35.67(f) provides that a licensee need not perform a leak test on certain specified sources.

Section 35.67(g) requires licensees in possession of sealed or brachytherapy sources, except for gamma stereotactic radiosurgery sources, to conduct a semi-annual physical inventory of all such sources in their possession. This section requires the licensee to retain each inventory record in accordance with § 35.2067.

The final rule also eliminates paragraphs §§ 35.59(h) and (i) in the current rule, which require quarterly measurement of ambient dose rates in areas where sealed sources or brachytherapy sources are stored and retention of records of surveys. Surveys continue to be required to be performed to demonstrate compliance with 10 CFR Part 20.

Cost Impacts: Cost savings, from reduction in frequency of required source inventory from quarterly to semiannually.

Assumptions:

Licensees: Total affected licensees: 1,876 [12]; Reduction in frequency of required source inventory, hours: 1; Technical staff hourly rate: $30; Total Annual Cost Savings from § 35.67: $56,000.

Health and Safety Impacts: None anticipated. The source inventory requirements of § 35.67(g) of the final rule, the requirements of 10 CFR 20.1501(a)(2)(iii), as well as the occupational dose and ALARA requirements of 10 CFR Part 20, adequately address ambient dose rate measurements in areas where sealed sources are stored.

Benefits: Cost savings to licensees and increased flexibility for licensees.

5.38 Labeling of vials and syringes (§ 35.69).

Section 35.60 currently requires that licensees keep syringes containing byproduct material conspicuously labeled and in a radiation shield that is also conspicuously labeled. Use of a syringe radiation shield is required when preparing and administering the radiopharmaceutical.

Section 35.61 currently requires that licensees preparing or handling vials containing byproduct material keep them conspicuously labeled and in a vial radiation shield that is also conspicuously labeled.

The final rule deletes §§ 35.60 and 35.61 and replaces them with a new § 35.69. The final rule requires that each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield also must be labeled unless the label on the syringe or vial is visible when shielded.

Cost Impacts: None anticipated. Licensees are expected to rely on labeling of vials and syringes by suppliers or in-house nuclear pharmacies and to properly label shields for vials and syringes. Labeling under the final rule is expected to require approximately the same time as under the current rule.

Health and Safety Impacts: None anticipated.

Benefits: Increased flexibility for licensees.

5.39 Surveys of ambient radiation exposure rate (§ 35.70).

Section 35.70 currently provides specific requirements for licensees to conduct daily and weekly surveys.

Section 35.70(a) of the final rule requires, in addition to the surveys required by Part 20, that a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct materials requiring a written directive were prepared for use or administered.

Section 35.70(b) provides that a licensee does not need to perform the surveys required by § 35.70(a) in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

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[12] Sum of licensees in Program Codes 2110, 2210, 2230, 2231, and 2300; plus 30 percent of licensees in Program Codes 2120 and 2200, estimated as possessing multiple sources. Program Codes 2121 and 2201 were not included because sealed sources in their possession are likely used and recorded daily, such as for dose calibrator calibration.

Section 35.70(c) requires licensees to retain a record of each survey in accordance with § 35.2070.

The final rule also eliminates in their entirety paragraphs §§ 35.70(b)–(g) in the current rule.

Cost Impacts: None anticipated.

Health and Safety Impacts: No health or safety impact is anticipated from this amendment. NRC assumes most 10 CFR Part 35 licensees will continue to conduct adequate surveys as part of their radiation protection program.

Benefits: Increased flexibility for licensees.

5.40 Release of individuals containing unsealed byproduct material or implants containing byproduct materials (§ 35.75).

Section 35.75 currently requires the following:

(a) The licensees may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem).

(b) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were not interruption of breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding and

(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered,

(2) Using an occupancy factor less than 0.25 at one meter,

(3) Using the biological or effective half-life, or

(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts (0.5 rem).

The final rule essentially retains § 35.75 and provides that records of the release of individuals containing unsealed byproduct material or implants containing byproduct material are to be maintained in accordance with §§ 35.2075(a) and (b). Section 35.75 also makes the following changes in the final rule: (1) eliminates "permanent" from the § 35.75(a); (2) adds "parent or guardian" to § 35.75(b); (3) adds "potential" and "if any" to § 35.75(b)(2); (4) revises the record requirements in § 35.75(c); and (5) adds references to the recordkeeping requirements in §§ 35.2075(a) and (b) to §§ 35.75(c) and (d), respectively.

Cost Impacts: No incremental costs or cost savings are anticipated with § 35.75 for licensees, Agreement States, or NRC.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

5.41 Provision of mobile medical service (§ 35.80).

Section 35.80 currently provides technical requirements for mobile medical service. Section 35.29 currently specifies the requirements for licensing mobile nuclear medicine services.

The final rule is revised as follows:

Sections 35.80(a), (b), and (c) of the current rule are eliminated.

Section 35.80(a) of the final rule includes a requirement previously included in § 35.29(b) of the current rule that licensees providing mobile medical services must obtain a letter from each client's management permitting and agreeing to the services, including a discussion of each entity's responsibilities. The final rule eliminates the requirement from Part 35 that a licensee transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits; the requirement that the licensee bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste; the requirement that the licensee secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use; and the requirement that the licensee carry a radiation detection survey meter in

each vehicle used to transport byproduct material. The final rule continues to require licensees to check instruments used to measure the activity of unsealed byproduct materials, specifying that such checks occur before medical use at each client's address or on each day of use, whichever is more frequent; requires survey instruments to be checked for proper operation with a dedicated check source before use at each client's address; and before leaving a client's address of use, to survey all areas of use, to ensure compliance with the requirements in 10 CFR Part 20.

Section 35.80(b) prohibits a mobile medical service from having byproduct material delivered from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the byproduct material. This section requires that byproduct material delivered to the client's address of use shall be received and handled in conformance with the client's license.

Section 35.80(c) requires the letter required in paragraph § 35.80(a)(1) to be retained and the record of each survey required in paragraph (a)(4) to be retained in accordance with § 35.2080.

Cost Impacts: Section 35.29 has been eliminated and replaced with requirements in final §§ 35.18(b) and 35.80. Under § 35.80, licensees may be required to incur costs to obtain a dedicated check source, although in many cases such sources will be supplied with the survey instruments. Licensees also may already possess check sources, because the current rule requires instruments to be checked for proper operation. Therefore, minimal cost impacts (i.e., <$1,000) are expected.

Health and Safety Impacts: Elimination of the requirements currently in §§ 35.80(1)(a) through (c) is not expected to result in impacts to health or safety.

Benefits: Conforming change for restructuring of 10 CFR Part 35.

5.42 Storage of volatiles and gases (§ 35.90).

Section 35.90 currently requires licensees to store: (1) volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container; and (2) multi-dose containers in a fume hood after drawing the first dosage from it.

The final rule eliminates § 35.90.

Cost Impacts: None anticipated.

Health and Safety: None anticipated. Section 10 CFR 20.1701 currently requires licensees to use, to the extent practical, process or other engineering controls, such as containment or ventilation, to control the concentration of radioactive material in air, and 10 CFR 20.1702 requires use of other controls, if necessary, to control concentrations to values below those that define an airborne radioactivity area. Elimination of § 35.90 provides licensees with flexibility to determine the most effective method of storage. NRC anticipates that in general licensees continue to store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container and to store multi-dose containers in a fume hood.

Benefits: Increased flexibility for licensees.

5.43 Decay-in-storage (§ 35.92).

Section 35.92 currently allows licensees to hold byproduct material with a physical half-life of less than 65 days and dispose of it in ordinary trash, provided it follows specified handling procedures.

The final rule, in § 35.92(a), increases the maximum allowable half-life for byproduct material that may be held for decay in storage from 65 days to 120 days and eliminates a requirement that byproduct material must be held for decay in storage a minimum of ten half-lives. Section 35.92 of the final rule also eliminates the requirement to separate and monitor each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal. The final rule amends the requirement to remove or obliterate all radiation labels to specify that the licensee must remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste, after they have been released from the licensee.

Section 35.92(b) of the final rule requires licensees to retain a record of each disposal permitted under paragraph § 35.92(a) in accordance with § 35.2092.

Cost Impacts: Costs are expected to be avoided by the amendment to § 35.92(a) as a result of a reduced number of requests for license amendments to allow an exemption for 120 day half-life for holding material for a minimum of 10 half-lives. Numerous licensees have already obtained such amendments, although the precise number is not available. Therefore, relatively few are expected to be avoided annually in the future.

Assumptions:

Licensees: Total annual amendments avoided: 17; Technical staff preparation time, hours: 1; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $1,000.

NRC/Agreement States: NRC/Agreement States amendment review time, hours: 0.5; NRC/Agreement States staff hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States:$1,000; Total Annual Cost Savings from § 35.92: $2,000.

Health and Safety Impacts: None anticipated because licensees are expected to continue to monitor waste to ensure it has decayed to background radiation levels before disposal.

Benefits: Increased flexibility for licensees and reduced number of license amendments.

SUBPART D—UNSEALED BYPRODUCT MATERIAL—WRITTEN DIRECTIVE NOT REQUIRED

5.44 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required (§ 35.100).

The current rule, in § 35.100, permits a licensee to use for uptake, dilution, or excretion studies any unsealed byproduct material that is obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement States requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

The final rule amends § 35.100 by limiting the use of unsealed byproduct material for uptake, dilution, and excretion studies to medical uses that do not require a written directive pursuant to §§ 35.40(b)(1) or (2). It revises the references in § 35.100(b) to conform to the final rule. It allows the use of unsealed byproduct material that is obtained from a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements under §§ 35.290 or 35.390 or an individual under the supervision of either. The final rule adds a new section, § 35.100(c), specifying that material may be used that is obtained from and prepared by an NRC or Agreement State licensee in research in accordance with a Radioactive Drug Research Committee-approved (RDRC-approved) protocol or an Investigational New Drug (IND) protocol accepted by the FDA. It also adds a new section, § 35.100(d), specifying that material may be used that is prepared by the licensee for use in research in accordance with a RDRC-approved application or an IND protocol accepted by FDA.

Cost Impacts: None anticipated.

Health and Safety Impacts: None Anticipated.

Benefits: The final rule allows: (1) a medical use licensee to receive radioactive drugs, for use in RDRC-approved or IND research protocols, prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees; and (2) any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

5.45 Possession of survey instrument (§ 35.120).

The current rule, in § 35.120, requires each licensee to have in its possession a radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The final rule eliminates § 35.120.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts: None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits: Increased flexibility for licensees.

5.46 Training for uptake, dilution, and excretion studies (§ 35.190).

The current rule, in § 35.910, specifies the training requirements for an authorized user of a radiopharmaceutical for uptake, dilution, and excretion studies.

Section 35.910(a) lists five specialist boards through which an individual may become certified to perform these procedures.

Alternatively, § 35.910(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 40 hours of classroom and laboratory training in specified subjects. In addition, it requires 20 hours of supervised clinical experience.

Alternatively, § 35.910(c) specifies that the individual may complete a six month training program in nuclear medicine approved by the Accreditation Council for

Graduate Medical Education that includes the classroom, laboratory, and clinical requirements specified in paragraph (b).

The final rule, in § 35.190, provides the following:

The list of five approved speciality boards is eliminated. Section 35.190(a) provides instead that the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.190(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.190(b) acknowledges physicians who are authorized users under §§ 35.290 or 35.390 or equivalent Agreement State requirements as meeting the requirements of § 35.190.

Alternatively, under § 35.190(c), the physician must have completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies, including classroom and laboratory training in specified areas; must have work experience under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements in specified areas; and must have obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

The final rule eliminates the alternative of completing a six-month program approved by the Accreditation Council for Graduate Medical Education (§ 35.971).

Cost Impacts: NRC anticipates incremental costs associated with this section involving additional costs to NRC/Agreement States for recognizing specialty boards, to certification boards for preparing materials supporting their recognition, and to the authorized user for the cost of obtaining preceptor certifications.

NRC estimates that approximately 110 physicians seek to become authorized users under § 35.190 or equivalent Agreement State regulations annually. Of these, 90 percent, or 99 physicians, seek certification by a certifying board under § 35.190(a). No additional cost impacts are created for them under the final rule. NRC estimates that the remainder, or approximately 11 physicians, seek to become authorized users under § 35.190(c). New costs for securing a preceptor statement are created by the final rule.

The costs to NRC/Agreement States for recognizing specialty boards for purposes of § 35.190(a) are estimated below.

Assumptions:

NRC/Agreement States: Number of boards reviewed: 5; NRC/Agreement States review time: 4 hours/board at $75 per hour; Total Cost Increase: $2,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards seeking recognition 5; Preparation of submission: 12 hours/board for Technical Staff at $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $4,000; Total Cost Increase for § 35.190(a): $6,000.

The costs to licensees associated with securing a preceptor's certification for purposes of § 35.190(b) are estimated on the basis of 10 percent of candidates seeking authorization through § 35.190(b).

Assumptions:

Licensees: Number of candidates: 11; Cost of preceptor certification: ½ hour at $20 hour for candidate[13] plus ½ hour at $100/hour for preceptor; Total Cost Increase for § 35.190(b): $1,000; Total Cost Increase for § 35.190: $7,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.47 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required (§ 35.200).

The current rule, in § 35.200, permits a licensee to use for imaging and localization studies any unsealed byproduct material that is obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement States require-

[13] Candidate's time measured at $20 per hour based on a resident physician's estimated annual salary of $30,000 to $40,000.

ments, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

The final rule amends § 35.200 by limiting the use of unsealed byproduct material for imaging and localization studies to medical uses that do not require a written directive pursuant to § 35.40(b). It revises the references in § 35.200(b) to conform to the final rule. Section 35.200(b) allows the use of unsealed byproduct material that is obtained from a manufacturer or preparer licensed under § 32.72 or equivalent Agreement State requirements or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements under §§ 35.290 or 35.390 or an individual under the supervision of either as specified in § 35.27. The final rule adds a new section, § 35.200(c), specifying that material may be used that is obtained from and prepared by an NRC or Agreement State licensee in research in accordance with a Radioactive Drug Research Committee-approved (RDRC-approved) protocol or an Investigational New Drug (IND) protocol accepted by the FDA. The final rule also adds a new section, § 35.200(d), specifying that material may be used that is prepared by the licensee for use in research in accordance with a RDRC-approved application or an IND protocol accepted by FDA.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: The final rule allows: (1) a medical use licensee to receive radioactive drugs, for use in RDRC-approved or IND research protocols, prepared and distributed by NRC or Agreement State licensees who are not § 32.72 licensees; and (2) any individual to prepare a radioactive drug in accordance with either an RDRC-approved protocol or an IND protocol.

5.48 Permissible molybdenum–99 concentration (§ 35.204).

Section 35.204(a) of the current rule prohibits licensees from administering to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum–99 per millicurie of technetium–99m. Section 35.204(b) requires licensees using molybdenum–99/technetium–99m generators for preparing a technetium–99m radiopharmaceutical to measure the molybdenum–99 concentration of each eluate or extract.

The final rule, in § 35.204(a), changes the expression of the permissible concentration to provide that a licensee may not administer more than 0.15 kilobecquerel of molybdenum–99 per megabecquerel of technetium–99m (0.15 microcurie of molybdenum–99 per millicurie of technetium–99m). Section 35.204(b) requires that instead of each eluate, a licensee that uses molybdenum–99/technetium–99m generators must measure the molybdenum–99 concentration of the first eluate after receipt of a generator to demonstrate compliance with § 35.204(a). Licensees are required to retain records of each measurement in accordance with the requirements specified in § 35.2204.

Cost Impacts: Cost savings are anticipated from elimination of the requirement that licensees must measure the molybdenum–99 concentration of each eluate or extract.

NRC assumes that 591NRC licensees and 1,478 Agreement States licensees use molybdenum–99/technetium–99m generators. Under the final rule, sale or transfer of a generator will require the new owner or user to measure the concentration of the first eluate. Assuming that generators are replaced weekly, this amendment is expected to reduce the frequency of measurements from approximately one per day to about one per week.

Assumptions:

Licensees: Number of licensees: 2,069; Number of avoided eluate tests per licensee: 200; Time required to measure concentration of eluate, hours: 0.08; Technical staff hourly rate: $30; Total Annual Cost Savings from amendment to § 35.204: $993,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings to licensees.

5.49 Control of aerosols and gases (§ 35.205).

The current rule, in § 35.205(a), requires licensees to administer radioactive aerosols or gases in a room with a system that will keep airborne concentrations below the limits prescribed by 10 CFR 20.1201 and 20.1301. Section 35.205(c) requires that before receiving, using, or storing a gas, a licensee must calculate the amount of time needed after a spill to reduce the concentration to the limits specified in 10 CFR 20.1201, and § 35.205(d) requires the licensee to make a record of the calculations required by § 35.205(c) and retain that record for the duration of the use of the area.

The final rule eliminates § 35.205.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated. Licensees will continue to be required to meet the requirements for occupational dose limits for adults and dose limits for individual members of the public, as specified in 10 CFR 20.1201 and 20.1301, respectively.

Benefits: Regulatory flexibility for licensees.

5.50 Possession of survey instruments (Current § 35.220).

The current rule, in § 35.220, requires each licensee to have in its possession a radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

The final rule eliminates § 35.220.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts: None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits: Increased flexibility for licensees.

5.51 Training for imaging and localization studies (§ 35.290).

The current rule, in § 35.920, specifies the training requirements for an authorized user of radiopharmaceuticals and generators for imaging and localization studies.

Section 35.920(a) lists five specialist boards through which an individual may become certified to perform these procedures.

Alternatively, § 35.920(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. The regulations currently require 200 hours of classroom and laboratory work training (§ 35.920(b)(1)); 500 hours of supervised work experience (§ 35.920(b)(2)); and 500 hours of supervised clinical experience (§ 35.920(b)(3)).

Alternatively, § 35.920(c) specifies that the individual may complete a six month training program in nuclear medicine approved by the Accreditation Council for Graduate Medical Education that includes the classroom, laboratory, and clinical requirements specified in paragraph (b).

The final rule, in § 35.290, provides the following:

The list of five approved speciality boards is eliminated. Section 35.290 provides that except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician certified by a medical specialty board whose certification process includes all of the requirements in § 35.290(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.290(b) acknowledges physicians who are authorized users under § 35.390 or equivalent Agreement State requirements as meeting the requirements of § 35.290.

Alternatively, under § 35.290(c), the physician must have completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include classroom and laboratory training in specified areas and work experience, under the supervision of an authorized user who meets the requirements in § 35.290 or § 35.390 or equivalent Agreement State requirements, involving specified activities. The physician must have obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the classroom and laboratory training and work experience required under § 35.290(c) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

The final rule eliminates the alternative of completing a six-month training program approved by the Accreditation Council for Graduate Medical Education (§ 35.971).

Cost Impacts: Cost savings are associated with the final rule due to the reduction in required training hours. NRC assumes that the reduction in required hours will not be reflected in the educational process of the certifying boards.

NRC estimates that approximately 110 physicians will seek to become authorized users under § 35.290 or equivalent Agreement State regulations annually. Of these, 90 percent, or 99, will seek certification by a certifying board under § 35.290(a). No additional cost impacts be created for them under the final rule. NRC estimates that the remainder, or approximately 11 physicians, will seek to become authorized users under § 35.290(c). New costs for securing a preceptor statement are created by the

final rule. However, NRC assumes that individuals will seek certification under both §§35.190 and 35.290, and that, therefore, no additional costs for preceptor certification will be incurred because these costs are reflected under §35.190.

Additional costs to NRC/Agreement States are associated with the recognition of specialty boards and preparing the specialty board submission. Because both §§35.910(a) and 35.920(a) contain identical lists of certifying organizations, NRC assumes one review of each organization to satisfy the requirements of §§35.190(a) and 35.290(a). Therefore, the costs to NRC/Agreement States for recognizing specialty boards for purposes of §35.290(a) are estimated under §35.190(a).

The cost savings that will be realized under this section due to the reduction in training hours required in §35.290(c) are estimated below:

Assumptions:

Licensees: Number of candidates seeking certification through §35.290(c): 11; Training hours required under current rule: 1,200 at $20/hour; Training hours required under rule: 700 at $20/hour; Total Annual Cost Savings from §35.290: $238,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.52 Elimination of §35.971 of the current rule (Physician training in a three month program).

Section 35.971 of the current rule provides that a physician who began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education before July 1, 1984, and successfully completed the program was not required to comply with the requirements of §§35.910 or 35.920.

The final rule deletes §35.971.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Consistency with the revised training and experience requirements.

SUBPART E—UNSEALED BYPRODUCT MATERIAL—WRITTEN DIRECTIVE REQUIRED

5.53 Use of unsealed byproduct material for which a written directive is required (§35.300).

The current rule, in §35.300, provides that a licensee may use unsealed byproduct material prepared for medical use for therapeutic administration that is either obtained from a manufacturer or preparer licensed under §32.72 or equivalent Agreement State requirements, or prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §35.920, or an individual under the supervision of either as specified in §35.25.

Section 35.300 of the final rule is revised to indicate that it applies to any medical use of unsealed byproduct material for which a written directive is required. The final rule also changes the reference to the training and experience requirements for authorized users to §§35.290 or 35.390 and the reference to the regulatory requirements for supervision (§35.27). It adds two additional subsections indicating that it also applies to use of unsealed byproduct material obtained from NRC or an Agreement State licensee in accordance with an Investigational New Drug (IND) application accepted by FDA or prepared by the licensee for use in accordance with an IND protocol accepted by FDA for use in research.

Cost Impacts: None anticipated.

Health and Safety: None anticipated.

Benefits: Provides clarification that any medical use of unsealed byproduct material (e.g., diagnostic or therapeutic) requiring a written directive are included under this subpart. Also, the final rule allows specific licensees to obtain unsealed byproduct material prepared by other NRC or Agreement State licensees for use in medical research in accordance with an IND protocol accepted by the FDA.

5.54 Safety Instruction (§35.310).

Section 35.310(a) of the current rule requires safety instruction for all personnel caring for the patient or human research subject receiving radiopharmaceutical therapy and hospitalized under §35.75. Instruction is required in the following areas: (1) patient or human research subject control; (2) visitor control; (3) contamination control; (4) waste control; and (5) notification of the Radiation Safety Officer in case of patient death or medical emergency. Section 35.310(b) requires that the licensee retain records of individuals receiving instruction for 3 years.

The final rule adds a provision specifying that the requirements of §35.310 are in addition to the worker instruction requirements of 10 CFR 19.12. Section 35.310(a) provides that radiation safety instruction must be given initially and at

least annually to personnel caring for patients or human research subjects who cannot be released in accordance with § 35.75. Section 35.310(a) also specifies that such training must be commensurate with the duties of the personnel and what such training must include. Section 35.310(b) of the final rule requires records of persons receiving instruction to be retained in accordance with § 35.2310.

Cost Impacts: No cost impacts anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Increased radiation safety.

5.55 Safety Precautions (§ 35.315).

Section 35.315(a) currently specifies safety precautions that licensees must take for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75.

Section 35.315(a)(1) requires a private room with a private sanitary facility.

Section 35.315(a)(2) requires posting a "Radioactive Materials" sign on the patient's door and indicating on the door or in the patient's chart where and how long visitors may stay in the room.

Section 35.315(a)(3) authorizes visits by individuals under age 18 on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer.

Section 35.315(a)(4) requires the licensee to measure dose rates in contiguous areas promptly after administration of the dosage and retain for 3 years a record of each survey demonstrating compliance with 10 CFR Part 20.

Section 35.315(a)(5) requires the licensee to monitor items removed from the patient's room to determine that their radioactivity is not greater than background radioactivity or handle them as radioactive waste.

Section 35.315(a)(6) is reserved.

Section 35.315(a)(7) requires the licensee to survey the patient's room for removable contamination before assigning another patient the same room.

Section 35.315(a)(8) requires the licensee to measure the thyroid burden of each individual who helped prepare or administer a dosage of I–131 and retain a record of each measurement.

Section 35.315(b) requires a licensee to notify the Radiation Safety Officer if the patient has a medical emergency or dies.

The final rule makes the following changes to § 35.315:

Section 35.315(a) specifies licensee actions for each patient or human research subject who cannot be released in accordance with § 35.75.

Section 35.315(a)(1) requires the licensee to quarter the patient or human research subject in either: (1) a private room with a private sanitary facility or (2) a room with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released pursuant to § 35.75.

Section 35.315(a)(2) and (a)(3) require the patient's or the human research subject's room to be posted with a "Radioactive Materials" sign and a note on the door or in the patient's or human research subject's chart stating where and how long visitors may stay in the room.

Sections 35.315(a)(3) and (a)(4) in the current rule are eliminated.

Section 35.315(a)(5) in the current rule is renumbered as § 35.315(a)(4) in the final rule.

Sections 35.315(a)(6), (a)(7) and (a)(8) in the current rule are eliminated.

Section 35.315(b) clarifies that licensees shall notify the authorized user and the Radiation Safety Officer, or his or her designee, as soon as possible if the patient or human research subject has a medical emergency or dies.

Cost Impacts: Cost savings may exist from § 35.315(a)(1)(ii) allowing two patients who cannot be released to be quartered in the same room. Cost savings may be possible if, when medical institutions elect to quarter two patients together, they are able to slightly increase occupancy rates.

No cost impacts are anticipated from elimination of §§ 35.315(a)(3), (4), and (6)–(8) of the current rule. Licensees will continue to be required to comply with 10 CFR Part 20.

Health and Safety Impacts: None anticipated.

Benefits: Improved flexibility for licensees.

5.56 Possession of survey instruments (§ 35.320).

The current rule, in § 35.320, requires each licensee to have in its possession portable radiation detection survey instruments.

The final rule eliminates § 35.320.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts: None anticipated because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits: Increased flexibility for licensees.

5.57 Training for use of unsealed byproduct material for which a written directive is required (§ 35.390).

The current rule, in § 35.930, specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I–131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I–131 for treatment of thyroid carcinoma in three individuals.

The final rule renumbers § 35.930 as § 35.390 and makes the following changes:

The list of four approved speciality boards is eliminated. Section 35.390 provides that except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.390(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, the licensee shall require an authorized user to have completed the training and experience specified in § 35.390(b) and to have obtained written certification signed by a preceptor authorized user meeting certain specified requirements.

Section 35.390(b)(1) requires completion of 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. It specifies the topics in which classroom and laboratory training must occur and the areas in which work experience, under the supervision of an authorized user meeting specified requirements, must occur. Section 35.390(b)(1)(ii)(G) specifies that experience must include administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the categories for which the individual is requesting authorized user status, and lists four categories of administration in § 35.390(b)(1)(ii)(G)(1) through (G)(4).

Section 35.390(b)(2) replaces the current § 35.930(b)(2). Section 35.390(b)(2) requires that the individual obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.390(a) or specified sections of § 35.390(b), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in § 35.390(b) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300.

Cost Impacts: The cost impacts associated with this section involve additional costs to NRC/Agreement States for recognition of certifying specialty boards, and to certifying boards for preparing materials supporting their recognition. Some individuals seeking to be an authorized user will incur costs for additional training and for preceptor certification.

NRC estimates that approximately 100 physicians will seek to become authorized users under § 35.390 or equivalent Agreement State regulations annually. Of these, 95 percent will seek certification by a certifying board under § 35.390(a). Training currently accepted by the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association includes more than 700 hours of classroom and laboratory training and practical experience. Therefore, no additional costs will be incurred by these applicants to satisfy the new 700 hour training and experience requirement in § 35.390(b). The remaining five percent, an estimated four physicians, will seek to become authorized users by satisfying the training and experience requirements in § 35.390(b). They will incur costs for the additional 620 hours of training and experience required under the final rule and for obtaining a preceptor certification.

Costs to NRC/Agreement States for recognizing specialty boards for purposes of § 35.390(a) are estimated below.

Assumptions:

NRC/Agreement States: Number of boards reviewed: 1; NRC/Agreement States review time:4 hours/board at $75 per hour; Total Cost Increase: <$1,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards reviewed: 1; Preparation of submission: 12 hours/board for Technical Staff at $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $1,000; Total Cost Increase for § 35.390(a): $1,000.

NRC estimates that approximately four applicants, will seek to become authorized users under § 35.390(b). The costs to licensees associated with training and securing a preceptor's certification for purposes of § 35.390(b) are estimated below.

Costs to applicants for additional training and experience:

Assumptions:

Licensees: Total licensees: 5; Number of additional hours of training required: 620; Authorized user candidate hourly rate: $20; Total Cost Increase from additional training requirements for § 35.390(b): $62,000.

New costs for securing a preceptor statement under § 35.390(b) are created by the final rule.

Assumptions:

Licensees: Number of candidates: 5; Cost of preceptor certification (½ hour of preceptor's time at $100/hour plus ½ hour of candidate's time at $20/hour): $60; Cost Increase for obtaining preceptor certification under § 35.390(b): <$1,000; Total Cost Increase for § 35.390: $63,000.

Health and Safety Impacts: TNone anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.58 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) (§ 35.392).

The current rule, in § 35.930, specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material and in § 35.932 specifies the training requirements for an authorized user of iodine–131 for the treatment of hyperthyroidism.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I–131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I–131 for treatment of thyroid carcinoma in three individuals.

Section 35.932 specifies that the licensee shall require the authorized user of only iodine–131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine–131 for treating hyperthyroidism and supervised clinical experience consisting of 80 hours of classroom and laboratory training that includes specified subjects, and also supervised clinical experience under the supervision of an authorized user that includes the use of iodine–131 for diagnosis of thyroid function and the treatment of hyperthyroidism in 10 individuals.

The final rule creates a new § 35.392 providing the following:

Section 35.392(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I–131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries) to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.392(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.392(b) provides that the licensee shall require an authorized user to be an authorized user under §§ 35.390(a), 35.390(b), for uses listed in §§ 35.390(b)(1)(ii)(G)(1) or (2), or 35.394 or equivalent Agreement State requirements.

Alternatively, § 35.392(c) provides that the licensee shall require an authorized user to have: (1) successfully completed 80 hours of classroom and laboratory training in specified subjects; (2) work experience under the supervision of an authorized user who meets specified requirements involving specified activities, including ad-

ministering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131; and (3) obtained written certification, signed by a preceptor authorized user who meets specified requirements, that the individual has successfully completed the classroom and laboratory and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I–131.

Cost Impacts: NRC anticipates incremental costs associated with this section involving additional costs to NRC/Agreement States for certifying medical specialty boards. NRC anticipates costs to the physicians seeking authorized user status from obtaining the preceptor's certification.

NRC estimates that approximately 100 physicians will seek to become authorized users under § 35.392 or equivalent Agreement State regulations annually. Of these, 90 percent will seek certification by a certifying board under § 35.392(a). No additional cost impacts be created for them under the final rule. NRC estimates that the remainder, approximately 10 physicians, will seek to become authorized users under § 35.392(c). New costs for securing a preceptor statement are created by the final rule.

Costs to NRC/Agreement States for recognizing specialty boards for purposes of § 35.392(a) are estimated below.

Assumptions:

NRC/Agreement States: Number of boards reviewed: 2; NRC/Agreement States review time:4 hour/board at $75 per hour; Total Cost Increase: $1,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards reviewed: 2; Preparation of submission: 12 hours/board for Technical Staff at $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $2,000; Total Cost Increase for § 35.392(a): $3,000.

New costs for securing a preceptor statement under § 35.392(c) are created by the final rule.

Assumptions:

Licensees: Number of candidates: 10; Cost of preceptor certification (½ hour of preceptor's time at $100/hour plus ½ hour of candidate's time at $20/hour): $60; Cost Increase for obtaining preceptor certification under § 35.392(c): $1,000; Total Cost Increase for § 35.392: $4,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.59 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) (§ 35.394).

The current rule, in § 35.930, specifies the training requirements for an authorized user of radiopharmaceuticals for therapeutic administration of unsealed byproduct material, and, in § 35.934, specifies the training requirements for use of iodine–131 for the treatment of thyroid carcinoma.

Section 35.930(a) lists four specialist boards through which an individual may become certified.

Alternatively, § 35.930(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 80 hours of classroom and laboratory training in specified subjects. In addition, it requires supervised clinical experience, including use of I–131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals and use of I–131 for treatment of thyroid carcinoma in three individuals.

Section 35.934 specifies that the licensee shall require the authorized user of only iodine–131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine–131 for treating thyroid carcinoma and supervised clinical experience consisting of 80 hours of classroom and laboratory training that includes specified subjects, and also supervised clinical experience under the supervision of an authorized user that includes the use of iodine–131 for the treatment of thyroid carcinoma in five individuals.

The final rule creates a new section, § 35.394, providing the following:

Section 35.394(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.394(c) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.394(b) provides that the licensee shall require an authorized user to be an authorized user under § 35.390(a), § 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements.

Alternatively, § 35.394(c) provides that the licensee shall require an authorized user to have: (1) successfully completed 80 hours of classroom and laboratory training in specified subjects; (2) have work experience under the supervision of an authorized user who meets specified requirements involving specified activities, including administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I–131; and (3) have obtained written certification, signed by a preceptor authorized user who meets specified requirements, that the individual has successfully completed the classroom and laboratory and work experience requirements and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300.

Cost Impacts: NRC anticipates that the medical boards recognized under § 35.392 will also seek recognition under this section. Therefore, no incremental costs will be associated with this section involving costs to NRC/Agreement States for certifying medical specialty boards. NRC anticipates costs to the physicians seeking authorized user status under § 35.394(c) from obtaining the preceptor's certification.

New costs for securing a preceptor statement under § 35.394(c) are created by the final rule. However, NRC assumes that candidates under § 35.394 will also seek to qualify under § 35.392, and therefore the costs of preceptor certification are reflected under § 35.392.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

SUBPART F—MANUAL BRACHYTHERAPY

5.60 Use of sealed sources for manual brachytherapy (§ 35.400).

Section 35.400 currently requires a licensee to use specified sources for brachytherapy in accordance with the manufacturer's radiation safety and handling instructions. Section 35.400 approves the use of seven sealed sources for brachytherapy and specifies how they may be used (e.g., topically, interstitially).

The final rule amends § 35.400 to eliminate the listing of permissible sealed sources and therapeutic use specifications. It replaces the list with the provision that a licensee shall only use brachytherapy sealed sources for therapeutic medical uses as approved in the Sealed Source and Device Registry (SSDR) or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Cost Impacts: Cost savings are associated with this section in the final rule. Use of a brachytherapy source or employment of a brachytherapy therapeutic treatment method not listed in § 35.400 currently requires a license amendment. The final rule eliminates the need for a licensee to obtain a license amendment to use a source or therapeutic method not listed in § 35.400. No longer requiring licensees to submit license amendments if they want to use a source or therapeutic method not listed in § 35.400 reduces both licensee costs and NRC and Agreement States costs.

Assumptions:

Licensees: Total number of amendments (10 NRC and 25 Agreement States licensees): 35; Licensee amendment preparation time, hours: 2; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $2,000.

NRC/Agreement States: Total license amendment submittals (10 NRC and 25 Agreement States licensees): 35; NRC/Agreement States amendment review time, hours: 1; NRC/Agreement States staff hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States: $2,000; Total Annual Cost Savings from changes to § 35.400: $4,000.

Health and Safety Impacts: Physicians have a wider range of therapeutic options and the methods in which the sealed sources can be used will increase. Use of new or revised techniques no longer require a license amendment, if the manufacturer updates the SSDR.

Benefits: Improved licensee flexibility and cost savings to licensees due to the elimination of license amendments.

5.61 Surveys after source implant and removal (§ 35.404).

Section 35.404(a) currently specifies that immediately after removing the last temporary implant source, the licensee must make a radiation survey of the patient or human research subject to confirm that all sources have been removed. The final rule provides that a licensee may not release a patient treated with temporary implants from confinement for medical care until all sources have been removed. Section 35.404(b) requires licensees to retain records of surveys.

Section 35.404(a) of the final rule specifies that immediately after implanting sources, the licensee must make a radiation survey to locate and account for all sources that have not been implanted. The final rule in § 35.404(b) specifies that immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

The final rule also eliminates the requirement that patients with temporary implants cannot be released until all implants have been removed. In the final rule, all requirements regarding the release of patients with temporary implants are contained in § 35.75. Section 35.404(c) requires licensees to retain a record of patient or human research subject surveys in accordance with § 35.2404.

Cost Impacts: Currently, a license amendment is required to allow for the release from hospital confinement of patients with temporary implants that have not been removed. The NRC anticipates cost savings for both licensees and NRC and Agreement States with the changes to § 35.404 in the final rule eliminating the requirement that the licensee may not release from confinement a patient or a human research subject treated by temporary implant until all sources have been removed. These cost savings result from no longer requiring the submission of license amendments to allow the release of patients with temporary implants that have not been removed.

Assumptions:

Licensees: Total number of amendments (10 NRC and 25 Agreement States licensees): 35; Licensee amendment preparation time, hours: 2; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $2,000.

NRC and Agreement States: Total license amendment submittals (10 NRC and 25 Agreement States licensees): 35; NRC/Agreement States amendment review time, hours: 1; NRC/Agreement States staff hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States: $3,000; Total Annual Cost Savings from changes to § 35.404: $5,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings and reduced regulatory burden due to the elimination of license amendments.

5.62 Brachytherapy sources accountability (§ 35.406).

Section 35.406(a) currently requires a licensee to return brachytherapy sources to the storage area promptly after removal and to count the number of sealed sources to ensure all sources taken from the storage area have been returned. Sections 35.406(b)(1)–(3) describe the specific records that must be kept concerning the use of the source. Section 35.406(c) requires a radiation survey of the patient and area of use immediately following a source implantation and § 35.406(d) mandates that these inventory and survey records must be kept for 3 years.

The final rule, in § 35.406, eliminates the requirement for a count of sources returned to the storage area. The final rule eliminates detailed specifications for the source inventory and survey requirements of the current rule. The final rule removes the requirement for a radiation survey immediately following a source implant from § 35.406(c) of the current rule and moves it to § 35.404(a) of the final rule.

Section 35.406(a) of the final rule requires licensees to maintain accountability at all times for all brachytherapy sources in storage or use.

Section 35.406(b) of the final rule requires licensees to return brachytherapy sources to a secure storage area, as soon as possible after removing sources from a patient or a human research subject.

Section 35.406(c) of the final rule requires that licensees make a record of brachytherapy source accountability in accordance with § 35.2406.

Cost Impacts: None anticipated. Licensees continue to be required to maintain accountability for each brachytherapy source.

Health and Safety Impacts: None anticipated. Licensees continue to be required to maintain records so that, if a brachytherapy source is misplaced or missing, the licensee is immediately alerted and can take appropriate action.

Benefits: Improved flexibility for licensees.

5.63 Safety instruction (§ 35.410).

Section 35.410 currently requires that radiation safety instruction be given to all personnel caring for patients or human research subjects undergoing implant therapy. Sections 35.410(a)(1)–(5) specify the subjects that must be covered in the instruction. Section 35.410(b) requires that records of individuals receiving instruction must be retained for 3 years.

The final rule amends § 35.410(a) to specify that radiation safety instruction must be provided to all personnel caring for patients who are receiving brachytherapy and cannot be released under § 35.75, and to require that the instruction be given "initially and at least annually." The instruction must be "commensurate with the duties of the personnel." Sections 35.410(a)(1)–(5) specifies the topics for instruction. Section 35.410(a)(5) adds a requirement that an authorized user, as well as the RSO or the RSO's designee, be notified if the patient or human research subject has a medical emergency or dies. Section 35.410(b) requires records to be maintained in accordance with § 35.2310.

Cost Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Increased radiation safety.

5.64 Safety precautions (§ 35.415).

Currently, § 35.415(a)(1) requires that implant patients confined to medical care may not be quartered with other hospital patients not receiving radiation therapy. Section 35.415(a)(2) stipulates that a sign "Radioactive Materials" and a note must be posted on an implant patient's door or chart regarding visiting instructions. Section 35.415(a)(3) requires that requests by minors to visit implant patients must be reviewed on a case-by-case basis by the authorized user in consultation with the RSO. Radiation surveys immediately following the implantation of a brachytherapy source to demonstrate compliance with 10 CFR Part 20 are required by § 35.415(a)(4) and immediate notification of the RSO upon patient death or patient medical emergency is required by § 35.415(b).

The final rule, in § 35.415(a), requires for each patient or human research subject who is receiving brachytherapy and cannot be released in accordance with § 35.75, a licensee shall: (1) not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy; (2) visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and (3) note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room. Section 35.415(b) of the final rule requires licensees to have available, near each treatment room, emergency response equipment to respond to a source dislodged from the patient and lodged within the patient following removal of the source applicators. Section 35.415(c) provides that the licensee notify an authorized user and the RSO, or his or her designee, as soon as possible, if the patient or human research subject has a medical emergency or dies.

Cost Impacts: None anticipated.

Health and Safety: Safety will be enhanced by assuring that both the authorized user and the RSO must be notified.

Benefits: Enhanced safety and increased flexibility for licensees.

5.65 Possession of survey instrument (§ 35.420).

The current rule, in § 35.420, requires each licensee to have in its possession a portable radiation detection survey instrument.

The final rule eliminates § 35.420.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts: None anticipated because licensees will continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits: Increased flexibility for licensees.

5.66 Calibration measurements of brachytherapy sources (§ 35.432).

The final rule adds a new section, § 35.432(a), that requires that before the first medical use of a brachytherapy source a licensee shall determine the source output or activity using a dosimetry system that meets the requirements of § 35.630(a) and

determine source positioning accuracy within applicators. Section 35.432(a)(3) requires these determinations to be made using published protocols accepted by nationally recognized bodies. Alternatively, § 35.432(b) of the final rule allows the licensee to use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with § 35.432(a). Section 35.432(c) requires the licensee to mathematically correct the outputs or activities determined under paragraph (a) for physical decay at intervals consistent with one percent physical decay. Section 35.432(d) requires that records of these calibration measurements be retained by licensees in accordance with § 35.2432.

NRC assumes that sources now provided by the manufacturer have been calibrated by the manufacturer in accordance with the requirements and licensees can rely on this calibration. Each licensee that chooses to calibrate its sources itself is estimated to spend approximately $1,000 annually to perform these calibrations and may need to purchase a new source calibration unit. Twenty percent of licensees are expected to calibrate sources currently in inventory or receive sources that require calibration.

Cost Impacts: Cost increases are anticipated from requirements in § 35.432 that require licensees using long-lived radionuclides to calibrate their sources. Only a very few of the affected licensees are not expected to have access to such a device and will need to purchase a new source calibrating unit.

Assumptions:

Licensees: Licensees purchasing source calibration device[14]: 51; Average cost of new source calibration unit[15]: $6,400; Total Cost Increase from Purchasing New Source Calibration Units: $326,000.

Cost increases are anticipated from requiring licensees using long-lived radionuclides to calibrate their sources.

Assumptions:

Licensees: Licensees calibrating sources[16]: 422; Annual source calibration cost: $1,000; Total Annual Cost Increase from source calibration: $422,000; Total Annual Cost Increase for § 35.432: $748,000.

Health and Safety Impacts: Enhanced safety. A required calibration measurement of brachytherapy sealed sources is expected to help ensure that the sealed source dose that is administered matches the prescribed dose.

Benefits: Enhanced safety.

5.67 Decay of strontium–90 sources for ophthalmic treatments (§ 35.433).

The final rule adds a new section, § 35.433, that provides that only an authorized medical physicist shall calculate the activity of each strontium–90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

Section 35.433(b) provides that the licensee shall retain a record of the activity of each strontium–90 source in accordance with § 35.2433.

Cost Impacts: Cost increases are anticipated from requiring that an authorized medical physicist must perform activity calculations.

Assumptions:

Licensees: Licensees for Strontium–90 eye applicators: 70; Medical physicist services: 1 hour/week/licensee at $100 per hour; Total Cost Increase for § 35.433: $364,000.

Health and Safety Impacts: Enhanced safety.

Benefits: Enhanced safety.

5.68 Therapy-related computer systems (§ 35.457).

The final rule adds a new section, § 35.457, that provides that the licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. The section specifies

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[14] 145 licensees in Program Codes 2210, 2230, and 2231 may need to own a calibrating unit for the first time. Adjusting by 2.5 to account for Agreement States yields 507. It was assumed that 10 percent of this number would not already own a calibrating unit and would need to purchase one.

[15] Personal communications with several manufacturers resulted in estimated prices for calibration units ranging from almost $6,000 to almost $7,000. An average rate of $6,400 per unit was used.

[16] 974 licensees in Program Codes 2110, 2120, and 2200 could perform brachytherapy. Assuming 60 percent actually do brachytherapy yields 584. Twenty licensees in Program Code 2210 also perform brachytherapy. Adjusting by 2.5 to account for Agreement States yields 2114. Twenty percent, or 422, are expected to calibrate sources currently in inventory or receive sources that require calibration.

that at a minimum the acceptance testing must include, as applicable: (1) verification of the source-specific input parameters required by the dose calculation algorithm; (2) the accuracy of dose, dwell time, and treatment time calculations at representative points; (3) the accuracy of isodose plots and graphic displays; and (4) the accuracy of the software used to determine radioactive source positions from radiographic images.

Cost Impacts: Minimal cost increases are anticipated from this section of the final rule because licensees currently perform acceptance testing according to procedures established by software providers.

Health and Safety Impacts: Enhanced safety.

Benefits: Enhanced safety.

5.69 Training for use of manual brachytherapy sources (§ 35.490).

The current rule, in § 35.940, specifies the training requirements for an authorized user of brachytherapy sources.

Section 35.940(a) lists four specialist boards through which an individual may become certified to become an authorized user of brachytherapy sources.

Section 35.940(b) specifies training and experience requirements that may be met in lieu of certification by one of the five listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 500 hours of specific, supervised work experience. Finally, the current rule also requires 3 years of supervised clinical experience to include: (1) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contradictions; (2) selecting the proper manual brachytherapy sources and dose and method of administration; (3) calculating the dose; and (4) post-administration follow up and review of case histories in collaboration with the authorized user.

The final rule creates a new § 35.490 providing the following:

The list of four approved speciality boards is eliminated. Section 35.490(a) provides that, except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who is certified by a medical specialty board whose certification process includes all of the requirements in § 35.490(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.490(b) provides that the licensee shall require an authorized user to have: (1) completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes 200 hours of classroom and laboratory training in specified subjects; (2) 500 hours of work experience under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution involving specified activities; and (3) obtained 3 years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience. In addition, the physician must obtain written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in §§ 35.490(b)(1) and (b)(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

Cost Impacts: NRC anticipates incremental costs associated with recognizing specialty boards. NRC also anticipates costs to the physicians seeking authorized use status under § 35.490(b) for obtaining a preceptor certification.

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.490 or equivalent Agreement State regulations annually. Of these, 95 percent, or 143, will seek certification by a certifying board under § 35.490(a). No additional cost impacts will be created for them under the final rule. NRC estimates that the remainder, or approximately seven physicians, will seek to become authorized users under § 35.490(b). New costs for securing a preceptor statement will be created by the final rule.

Assumptions:

NRC/Agreement States: Number of boards reviewed: 3; NRC/Agreement States review time: 4 hours/board at $75 per hour; Total Cost Increase for § 35.490(a): $1,000.

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.490(b) are estimated below.

Assumptions:
Licensees: Number of candidates: 7; Cost per preceptor statement (½ hour of preceptor's time plus ½ hour of candidate's time): $60; Total Cost Increase for § 35.490(b): <$1,000; Total Cost Increase for § 35.490: $1,000.
Health and Safety Impacts: None anticipated.
Benefits: Training and experience commensurate with risk and focused on radiation safety.

5.70 Training for ophthalmic use of strontium–90 (§ 35.491).

The current rule, in § 35.941, specifies the training requirements for ophthalmic use of strontium–90.
Section 35.941 of the current rule provides that, except as provided in § 35.970, the licensee shall require the authorized user of only strontium–90 for ophthalmic radiography to be a physician who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium–90 for ophthalmic radiotherapy, and supervised clinical training in ophthalmic radiotherapy that includes: (1) 24 hours of classroom and laboratory training in specified subjects; and (2) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium–90 for the ophthalmic treatment of five individuals that includes examination of each individual to be treated, calculation of the dose to be administered, administration of the dose, and follow-up and review of each individual's case history.
The final rule creates a new § 35.491 providing the following:
Section 35.491 substitutes § 35.57 for § 35.970 in the initial sentence, but otherwise incorporates the requirements in the current § § 35.941(a) and (b) into the final rule's § § 35.491 (a) and (b), respectively. A new paragraph, 35.491(b)(3) is added, requiring an individual to obtain written certification, signed by a preceptor authorized user who meets the requirements in § § 35.490, 35.491, or equivalent Agreement State requirements, that the individual has successfully completed the requirements in § 35.491 and has achieved a level of competency sufficient to function independently as an authorized user of strontium–90 for ophthalmic use.
Cost Impacts: NRC anticipates incremental costs associated with recognizing specialty boards. NRC also anticipates costs to the physicans seeking authorized user status for obtaining a preceptor certification. NRC estimates that approximately 15 physicians will seek to become authorized users under § 35.491 or equivalent Agreement State regulations annually. All will incur costs for securing a preceptor statement.
The costs to applicants associated with securing a preceptor's certification for purposes of § 35.491(c) are estimated below.
Assumptions:
Licensees: Number of candidates: 15; Cost per preceptor statement (½ hour of preceptor's time plus ½ hour of candidate's time): $60; Total Cost Increase for § 35.491(c): $1,000; Total Cost Increase for § 35.491: $1,000.
Health and Safety Impacts: None anticipated.
Benefits: Training and experience commensurate with risk and focused on radiation safety.

SUBPART G—SEALED SOURCES FOR DIAGNOSIS

5.71 Use of sealed sources for diagnosis (§ 35.500).

Section 35.500 currently requires a licensee to use specified sources for diagnosis in accordance with the manufacturer's radiation safety and handling instructions. Section 35.500 approves four medical uses of sealed sources for diagnostic procedures and specifies how the sources may be used.
The final rule, in § 35.500, eliminates the listing of permissible sealed sources and specifies that a licensee may use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.
Cost Impacts: The NRC anticipates cost savings with the changes to § 35.500. No longer requiring licensees to submit license amendments each time they want to use a source for a specific designated application not listed in § 35.500 will reduce both licensee costs and NRC and Agreement States costs.
Assumptions:
Licensee: Total licensees seeking amendments (5 NRC and 13 Agreement States licensees): 18; Licensee amendment preparation time, hours: 2; Technical staff hourly rate: $30; Total Annual Cost Savings for licensees: $1,000.
NRC/Agreement States: Total license amendment submittals (5 NRC and 13 Agreement States licensees): 18; NRC/Agreement States amendment review time,

hours: 1; NRC/Agreement States staff hourly rate: $75; Total Annual Cost Savings for NRC and Agreement States:$1,000; Total Annual Cost Savings from changes to § 35.500: $2,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings and increased licensee flexibility for licensees.

5.72 Availability of survey instrument (§ 35.520).

The current rule, in § 35.520, requires each licensee to have in its possession a portable radiation detection survey instrument.

The final rule eliminates § 35.520.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts: None anticipated, because licensees must continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits: Increased flexibility for licensees.

5.73 Training for use of sealed sources for diagnosis (§ 35.590).

The current rule, in § 35.950, specifies the training requirements for an authorized user of sealed sources for diagnosis.

Section 35.950(a) lists four specialist boards through which an individual may become certified to use sealed sources for diagnosis.

Section 35.950(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 8 hours of classroom and laboratory training in basic radioisotope handling techniques.

The final rule makes the following changes:

The specific list of four approved speciality boards is eliminated. Section 35.590(a) of the final rule provides instead that the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who is certified by a speciality board whose certification process includes all of the requirements in § 35.590(b) and whose certification has been recognized by the Commission or an Agreement State.

Alternatively, § 35.590(b), requires 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that include: (1) radiation physics and instrumentation; (2) radiation protection; (3) mathematics pertaining to the use and measurement of radioactivity; (4) radiation biology; and (5) training in the use of the device for the uses requested..

Cost Impacts: No cost impacts are expected to be associated with this section. The medical specialty boards providing certification under this section are expected to have been recognized under other sections of the final rule.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

SUBPART H—PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

5.74 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit (§ 35.600).

Section 35.600 currently regulates the use of teletherapy units for medical use that contain a sealed source of cobalt–60 or cesium–137.

The final rule amends the title and text of § 35.600 to include remote afterloader units and gamma stereotactic radiosurgery units, as well as teletherapy units, in Subpart H. The final rule eliminates the references to a sealed source of cobalt–60 or cesium–137 and specifies instead that a licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units: (1) as approved in the Sealed Source and Device Registry; or (2) in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Improved flexibility for licensees.

5.75 Surveys of patients and human research subjects treated with a remote afterloader unit (§ 35.604).

The final rule adds a new § 35.604 pertaining to radiation surveys for remote afterloaders. Section 35.604(a) requires that before releasing a patient or human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation

detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position. Section 35.604(b) requires licensees to retain a record of these surveys in accordance with § 35.2404.

Cost Impacts: None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Improved regulatory efficiency and consistency.

5.76 Installation, maintenance, adjustment, and repair (§ 35.605).

Section 35.605 requires that only persons specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair can: (1) install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or (2) maintain, adjust, or repair the source drawer, shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

The final rule adds remote afterloader units and gamma stereotactic radiosurgery units to the types of units covered by this section. Section 35.605(a) provides that only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

Section 35.605(b) of the final rule provides that except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

A new § 35.605(c) is added to provide that only a person specifically licensed by NRC or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in a low dose-rate remote afterloader unit.

A new § 35.605(d) provides that a record of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units must be retained in accordance with § 35.2605.

Cost Impacts: None anticipated. Section 35.605(a) makes no change with respect to teletherapy. It adds requirements for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloaders and gamma stereotactic radiosurgery. However, these requirements are consistent with current license conditions.

Section 35.605(c) creates a new exemption for low dose-rate remote afterloaders from the requirement that maintenance and repair personnel must be specifically licensed, by providing that authorized medical physicists may install, replace, relocate, or remove sources contained in low dose-rate remote afterloaders. This is anticipated to provide a small savings for licensees using a new source for every treatment.

Health and Safety Impacts: No health or safety impacts are anticipated. Maintenance and repair will continue to be performed only by qualified personnel.

Benefits: Improved flexibility and a small cost savings for licensees.

5.77 License amendments (§ 35.606).

The current § 35.606 requires a licensee to apply for and receive a license amendment before making any change in the treatment room shielding; making any change in the location of the teletherapy unit within the treatment room; using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room; relocating the teletherapy unit; or allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

The final rule eliminates § 35.606.

Cost Impacts: No significant cost impacts are anticipated.

Health and Safety Impacts: None anticipated. Occupational exposure and control of exposure and control of access continue to be covered by the requirements of 10 CFR Part 20.

Benefits: Improved flexibility for licensees.

5.78 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.610).

Section 35.610 currently establishes safety instruction requirements for teletherapy units. Section 35.610(a) requires that instructions regarding the proper op-

eration of a teletherapy unit must be posted at the unit console. In addition, § 35.610(b) requires that operators of teletherapy units receive instruction. Section 35.610(c) requires that records of individuals receiving training must be kept for 3 years.

The final rule amends the title and text of § 35.610. Section 35.610(a) requires that licensees secure the unit, the console, the console keys, and the treatment room when not in use or unattended; permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s); prevent dual operation of more than one radiation producing device in a treatment room if applicable; and develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. New paragraphs (a)(4)(i) through (iii) specify what the procedures must include.

New § 35.610(b) provides that a copy of the procedures required by paragraph (a)(4) must be physically located at the unit console.

Section 35.610(c) requires licensees to post instructions at the unit console for individuals who operate the devices. These instructions inform the operator of the location of the procedures required by § 35.610(a)(4) and the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

Section 35.610(d) requires licensees to provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the procedures required by paragraph (a)(4) and the operating procedures for the unit.

Section 35.610(e) requires licensees to ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

Section 35.610(f) requires licensees to retain a record of individuals receiving instruction required by § 35.610(d), in accordance with § 35.2310.

Section 35.610(g) requires licensees to retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) in accordance with § 35.2610.

Cost Impacts: No incremental costs are associated with § 35.610. These requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory efficiency and consistency, as a result of codifying requirements previously used as license conditions.

5.79 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.615).

Section 35.615 currently specifies detailed access controls and equipment requirements, including radiation monitoring equipment, for teletherapy rooms. In particular, § 35.615(a) requires access control to teletherapy rooms and § 35.615(b) requires an electrical interlock system. Section 35.615(c) requires licensees to equip each entrance to the teletherapy room with a beam condition indicator light and § 35.615(d) requires licensees to install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status. Section 35.615(e) requires that each teletherapy room will be constructed or equipped to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

The final rule amends the title of the section to specify that the section pertains to remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. It eliminates requirements for equipping each entrance with a beam condition indicator light, permanent radiation monitoring, and associated record keeping requirements. The final rule also adds requirements for viewing and intercom systems for all modalities except low dose-rate remote afterloaders.

Section 35.615(e) provides that for licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

Sections 35.615(f)(1)–(4) establish requirements pertaining to remote afterloaders and gamma stereotactic radiosurgery units. Section 35.615(f)(1) requires for medium dose-rate and pulsed dose-rate remote afterloader units that an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and an authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained

to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

Section 35.615(f)(2) requires for high dose-rate remote afterloader units that an authorized user and an authorized medical physicist be physically present during the initiation of all patient treatments involving the unit; and that an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during continuation of all patient treatments involving the unit.

Section 35.615(f)(3) requires for gamma stereotactic radiosurgery units that an authorized user and an authorized medical physicist be physically present throughout all patient treatments involving the unit.

Section 35.615(f)(4) requires the licensee to notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

Section 35.615(g) requires applicable emergency response equipment to be available near each treatment room to respond to a source remaining in the unshielded position; or lodged within the patient following completion of the treatment.

Cost Impacts: The elimination of requirements in §§35.615 (a)–(e) of the current rule for beam condition indicator lights and permanent radiation monitoring are expected to be offset by new requirements for viewing and intercom systems. Therefore, no incremental cost impacts are expected from revisions to these sections. In addition, 10 CFR 20.1601 continues to require control measures for high radiation areas.

Future cost savings are expected to be associated with §35.615(f)(1). Under the final rule, an authorized user is allowed to leave a medium or pulsed dose-rate remote afterloader treatment following the treatment's initialization if a medical physicist and either an authorized user or an individual under the supervision of an authorized user who has been given specified training is immediately available during continuation of the patient treatment. Currently, the authorized user is required to remain for the duration of the procedure. Future cost savings will result from increased use of pulsed dose-rate and medium dose-rate remote afterloaders, which are used infrequently at present, and from the opportunity to rely on less expensive staff for immediate response availability.

Costs savings are expected to be associated with §35.615(f)(2). Under the final rule, an authorized user will be allowed to leave a high dose-rate remote afterloader procedure following procedure initialization if a physician with remote afterloader emergency response training is available to observe the procedure. Currently, the authorized user is required to remain for the duration of the procedure. Other requirements are consistent with current license conditions. Cost savings will result from the opportunity to rely on less expensive staff to be present during continuation of treatments involving the HDR afterloader.

Assumptions:

Licensees: Number of annual HDR treatment fractions (35,000 procedures with 4 fractions per procedure): 140,000; Time to complete fraction after initiation, hours: 0.0667; Net reduction in hourly rate[17]: $20; Total Annual Cost Savings from §35.615: $187,000.

Health and Safety Impacts: None anticipated.

Benefits: Improved flexibility and cost savings for licensees.

5.80 Possession of survey instrument (§35.620).

The current rule, in §35.620, requires a licensee authorized to use byproduct material in a teletherapy unit to have in its possession a portable radiation detection survey instrument.

The final rule eliminates §35.620.

Cost Impacts: None anticipated, because licensees are expected to continue to possess survey instruments.

Health and Safety Impacts: None anticipated, because licensees are expected to continue to meet the requirements in 10 CFR 20.1501 and 20.1502 and 10 CFR 30.33 requiring surveys and monitoring.

Benefits: Increased flexibility for licensees.

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[17] Difference between authorized user physician at $100/hour and a non-authorized user physician at $80/hour.

5.81 Dosimetry equipment (§ 35.630).

Section 35.630(a)(1) of the current rule specifies that dosimetry equipment must be calibrated after any servicing and every 2 years at a minimum by the NIST or any calibration laboratory accredited by the AAPM. Alternatively, § 35.630(a)(2) allows dosimetry equipment to be calibrated every 4 years and subsequently intercompared at an intercomparison meeting to dosimetry equipment calibrated within the past 2 years by NIST or any other calibration laboratory accredited by AAPM. In addition, the current rule requires that a dosimetry system be available for spot-check measurements. The spot-check system can be the same system used to meet the requirements in § 35.630(a). Finally, § 35.630(c) requires a record of each calibration, intercomparison, and comparison.

The final rule requires that, except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. Section 35.630(a) requires the system to be calibrated either: (1) using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or (2) by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration. Alternatively, the system must have been calibrated within the previous 4 years. Eighteen to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the previous 24 months by the National Institute of Standards and Technology (NIST) or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The final rule eliminates the requirement in the current rule that equipment comparison must take place during an intercomparison meeting.

Section 35.630(b) requires the licensee to have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with § 35.630(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirements of § 35.630(a).

Section 35.630(c) requires a record of each calibration, intercomparison, and comparison to be retained in accordance with § 35.2630.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Increased flexibility for licensees.

5.82 Full calibration measurements on teletherapy units (§ 35.632).

Section 35.632 currently requires licensees to perform full calibration measurements on each teletherapy unit, and provides specific requirements for such calibration measurements. Section 35.632(d) specifies that the calibration shall be performed according to certain protocols cited in the regulation.

The final rule amends § 35.632(d) to eliminate the citations to specific protocols and instead provides that the licensee shall make full calibration measurements in accordance with "published protocols accepted by nationally recognized bodies."

A new § 35.632(b)(4) requires "timer accuracy" instead of "timer constancy."

A new § 35.632(e) requires a licensee to mathematically correct the outputs determined in § 35.632(b)(1) for physical decay for intervals not exceeding one month for cobalt–60, six months for cesium–137, or at intervals consistent with one percent decay for all other nuclides.

A new § 35.632(f) requires full calibration measurements required by § 35.632(a) and physical decay corrections required by § 35.632(e) to be performed by the authorized medical physicist.

A new § 35.632(g) requires a licensee to retain a record of each calibration in accordance with § 35.2632.

Cost Impacts: None anticipated. The requirements in § 35.632 of the final rule do not differ substantially from the requirements in § 35.632 of the current rule.

Health and Safety Impacts: None anticipated.

Benefits: The amendment provides greater flexibility to licensees to adopt calibration protocols and avoid the problem that protocols cited in 10 CFR Part 35 may become outdated over time. NRC will experience regulatory efficiencies as a result of not being required to periodically amend § 35.632.

5.83 Full calibration measurements on remote afterloader units (§ 35.633).

The final rule adds a new section, § 35.633, providing detailed specifications for calibration measurements on remote afterloaders.

Sections 35.633(a)(1) and (2) of the final rule require full calibration measurements on a remote afterloader before the first medical use of the device and before medical use following certain specified conditions.

Sections 35.633(a)(3) and (a)(4) of the final rule require an additional calibration at intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloaders with sources whose half-life exceeds 75 days and at intervals not to exceed 1 year for low dose-rate remote afterloaders.

Section 35.633(b) specifies that full calibration measurements must include, as applicable, determination of output within specified limits, source positioning accuracy within specified limits, source retraction, length of source transfer tubes, timer accuracy and linearity, length of the applicators; and function of source transfer tubes, applicators, and transfer tube-applicator interfaces.

Section 35.633(c) requires the licensee to use the dosimetry system described in § 35.630(a) to measure the output.

Section 35.633(d) requires the licensee to make full calibration measurements required by § 35.630(a) in accordance with published protocols accepted by nationally recognized bodies.

Section 35.633(e) specifies that in addition to the requirements for full calibrations for low dose-rate remote afterloader units in § 35.633(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

Section 35.633(f) specifies that for low dose rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with §§ 35.633(a)–(e).

Section 35.633(g) requires licensees to mathematically correct the output measurements determined in the full calibration for physical decay at intervals consistent with one percent physical decay.

Section 35.633(h) provides that the full calibration measurements and physical decay corrections must to be performed by the authorized medical physicist.

Section 35.633(i) requires that a record of each calibration must be kept in accordance with § 35.2632.

Cost Impacts: None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.84 Full calibration measurements on gamma stereotactic radiosurgery units (§ 35.635).

The final rule adds a new section, § 35.635, that provides detailed specifications for calibration measurements on gamma stereotactic radiosurgery units.

Sections 35.635(a)(1) and (2) require full calibration measurements on a gamma stereotactic radiosurgery unit before the first medical use of the device and before medical use whenever spot-check measurements indicate the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; following replacement of the sources or reinstallation of the unit in a new location; and following any repair of the unit that includes removal of the sources or major repair of the components associated with the source assembly. In addition, calibrations are required at intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of the helmet and following any damage to a helmet.

Section 35.635(b) specifies the measurements that need to take place in the full calibration.

Section 35.635(c) requires that a licensee use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining measurements required in paragraph (b)(1) may be made using a dosimetry system that indicates relative dose rates.

Section 35.635(d) requires full calibration measurements to be in accordance with published protocols accepted by nationally recognized bodies.

Section 35.635(e) specifies requirements for mathematical correction of outputs.

Section 35.635(f) requires that full calibration measurements and physical decay corrections mandated by §§ 35.633(a) and (e), respectively, must be performed by the authorized medical physicist.

Section 35.635(g) requires that records of calibrations must be retained in accordance with § 35.2632.

Cost Impacts: None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.85 Elimination of former § 35.636:

Section 35.636 of the current rule requires that licensees check all teletherapy operation systems listed in § 35.634(d) promptly following an installation of a source. A safety check is also required promptly following a teletherapy unit change pursuant to § 35.606. Section 35.636(b) stipulates that if a teletherapy unit malfunction is detected, the device console must be locked in the off position. Section 35.636(c) requires the retention of records of facility checks following an installation of a source for 3 years.

The final rule eliminates § 35.636.

Cost Impacts: None anticipated. Requirements from this section are incorporated into § § 35.642, 35.643, 35.644, and 35.645 of the final rule.

Health and Safety Impacts: None anticipated.

Benefits: Improved regulatory efficiency by reducing redundancy of requirements.

5.86 Radiation surveys for teletherapy facilities (§ 35.641).

The current rule, in § 35.641, specifies detailed requirements for radiation surveys for teletherapy facilities.

The final rule eliminates § 35.641.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Increased flexibility for licensees.

5.87 Periodic spot-checks for teletherapy units (§ 35.642).

Section 35.634 of the current rule requires periodic spot-checks of teletherapy units to determine proper unit operation.

The final rule replaces the term "teletherapy physicist" with "authorized medical physicist."

Section 35.642(a) retains essentially the same requirements as § 35.634(a) of the current rule, except that § 35.642(a)(1) requires "timer accuracy" instead of "timer constancy." Section 35.642(b) retains the same requirements as § 35.634(b), except that the final rule requires that the procedures established by the authorized medical physicist be in writing. The amended § 35.642(c) eliminates the requirement that the licensee must keep a record of the reports detailing the results of teletherapy unit periodic spot-checks for 3 years. Section 35.642(d) retains essentially the same requirements as § 35.634(d), except that the final rule, in § 35.642(d)(3), uses the term "source exposure" instead of "beam indicator" and § 35.642(d)(4) adds "intercom systems." Section 35.642(d) adds a new requirement for safety spot-checks after each source installation. Section 35.642(d)(4) also requires the installation of intercom systems in teletherapy unit treatment rooms. The final rule provides in § 35.642(e) that if the results of the checks required in § 35.642(d) indicate the malfunction of any system, a licensee shall lock the console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. Section 35.642(f) requires records of each spot-check required by § 35.642(a) and § 35.642(d) and a record of the written procedures established by the authorized medical physicist for performing spot-checks, required by § 35.642(b), to be kept in accordance with § 35.2642.

Cost Impacts: No incremental costs are associated with § 35.642. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.88 Periodic spot-checks for remote afterloader units (§ 35.643).

The final rule adds a new section, § 35.643, that provides detailed specifications for periodic spot-checks for remote afterloader units.

Section 35.643(a) requires a periodic spot-check for each remote afterloader facility and on each unit. Section 35.643(a)(1) requires a spot-check before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader on a given day. Section 35.643(a)(2) requires a periodic spot-check before each patient treatment with a low dose-rate remote afterloader. Section 35.643(a)(3) requires a periodic spot-check for each facility and unit after each source installation.

Section 35.643(b) requires a licensee to perform the measurements required by § 35.643(a) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

Section 35.643(c) requires the licensee to have the authorized medical physicist review the results of each spot-check within 15 days of its completion.

Section 35.643(d) specifies the measurements and the systems that must be accounted for in a spot-check.

Section 35.643(e) requires that if the results of the checks required in § 35.643(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

Section 35.643(f) requires that a record of spot-checks, required by § 35.643(d), and a record of the procedures for performing spot-checks establish by the authorized medical physicist, required by § 35.643(b), be retained in accordance with § 35.2643.

Cost Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.89 Elimination of former § 35.643:

Section 35.643 of the current rule is eliminated in the final rule. Section 35.643 of the current rule stipulates that if a survey required under § 35.641 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in 10 CFR 20.1301, the licensee shall either equip the unit with stops or add additional shielding. Sections 35.643(a)(2) and (3) require the licensee to perform the survey required by § 35.641 again; and paragraph (3) includes in the report required by § 35.645, the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of § 35.643, and the results of the second survey.

Section 35.643(b) allows radiation levels to exceed those mandated by 10 CFR 20.1301 if a license amendment is applied for and issued.

The final rule eliminates the current § 35.643.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated, because 10 CFR Part 20, particularly Subparts C and D, establishing occupational and public dose limits will continue to apply.

Benefits: Improved flexibility for licensees.

5.90 Periodic spot-checks for gamma stereotactic radiosurgery units (§ 35.645).

Section 35.645, "Reports of teletherapy surveys, checks, tests, and measurements," of the current rule is eliminated. The final rule includes a new § 35.645 that requires periodic spot-checks for gamma stereotactic radiosurgery units.

Section 35.645(a)(1) requires spot-checks of each gamma stereotactic radiosurgery facility and on each unit monthly.

Section 35.645(a)(2) requires a periodic spot-check for gamma stereotactic radiosurgery facilities and units before each day of use.

Section 35.645(a)(3) requires spot-checks for gamma stereotactic radiosurgery facilities and units after each source installation.

Sections 35.645(b)(1) and (b)(2) require an authorized medical physicist to establish written procedures for performing spot-checks and to review the results of each spot-check required by § 35.645(a)(1) within 15 days of its completion. The authorized medical physicist need not actually perform the spot-check measurements.

Section 35.645(c)and (d) describe the measurements and the systems that have to be accounted for in spot-checks. Section 35.645(c) specifies the requirements for spot-checks under § § 35.645(a)(1) and § 35.645(d) specifies the requirements for spot-checks under (a)(2) and (a)(3).

Section 35.645(e) requires the licensee to arrange for repair as soon as possible of any system identified under paragraph (c) that is not working properly.

Section 35.645(f) requires that if the results of the checks required in (d) indicate the malfunction of any system, the licensee must lock the control console in the off position and not use the unit, except as necessary to repair, replace, or check the malfunctioning system.

Section 35.645(g) requires a licensee to retain a record of each spot-check required by § § 35.645(c) and (d), and a record of the procedures for performing spot-checks established by the authorized medical physicist, required by § 35.645(d), in accordance with § 35.2645.

Cost Impacts: None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.91 Elimination of the former § 35.645:

Section 35.645 of the current rule requires that records required by §§ 35.636, 35.641, 35.643, and full calibration measurements required in § 35.632 must be mailed to the appropriate NRC Regional Office.

The final rule eliminates § 35.645.

Cost Impacts: The elimination of the forwarding requirement results in savings to licensees, estimated below:

Assumptions:

Licensees: Number of mailings by licensees avoided annually: 60; Estimated cost per mailing: $20; Total Annual Cost Savings from elimination of the former § 35.645: $1,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings to licensees.

5.92 Additional technical requirements for mobile remote afterloader units (§ 35.647).

Requirements in the current § 35.647, "5-year inspection," are moved to § 35.655.

The final rule adds a new section establishing technical requirements for mobile remote afterloader units. Section 35.647(a) in the final rule requires all survey instruments to be checked before medical use at each licensee address of use or on each day of use, whichever is more frequent, and that all sources be accounted for before leaving from a client's address of use. Section 35.647(b) requires checks of each remote afterloader unit before use at each address of use. Section 35.647(b) specifies the checks that must be made. Section 35.647(c) requires licensees to ensure overall proper operation by conducting a simulated cycle of treatment before use at each address of use. Section 35.647(d) requires that if the results of the checks required in (b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. Section 35.647(e) requires a record of each check required by § 35.647(b) be kept in accordance with § 35.2647.

Cost Impacts: Cost impacts are not anticipated because of the small number (7) of licensees, and because the requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.93 Radiation surveys (§ 35.652).

Currently, § 35.641 requires a radiation survey before medical use, after each installation of a source in a teletherapy unit, and after making other changes to a teletherapy unit. Section 35.641(a) describes the scope of the survey and what operational conditions need to be verified. Section 35.641(b) requires that the teletherapy unit control be locked in the off position if the survey indicates that radiation levels exceed the limit set in 10 CFR 20.1301.

The final rule amends § 35.641 and renumbers it as § 35.652. Section 35.652(a) of the final rule requires that in addition to the survey requirement in 10 CFR 20.1501, a person licensed under this subpart shall make such surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed levels stated in the Sealed Source and Device Registry. Section 35.652(b) of the final rule requires that licensees make the surveys required in paragraph (a) at installation of a new source and following specified repairs. Section 35.652(c) requires licensees to retain records of radiation surveys in accordance with § 35.2652.

Cost Impacts: None anticipated. Requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.94 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units (§ 35.655).

Section 35.647 of the current rule stipulates that teletherapy units must be inspected and serviced during teletherapy source replacement or every 5 years, whichever comes first. Section 35.647(b) of the current rule requires that this inspection and servicing may only be performed by a individual licensed by the Commission or Agreement States.

The final rule amends § 35.647 and renumbers it as § 35.655. The final rule adds a requirement for inspection and servicing of gamma stereotactic radiosurgery units during source replacement or every 5 years, whichever comes first. Section 35.655(b) requires that the servicing must be performed only by persons specifically licensed by NRC or an Agreement State.

Section 35.655(c) requires that licensees keep a record of inspection and servicing in accordance with new § 35.2655.

Cost Impacts: None anticipated. Requirements are consistent with current licensee activities.

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency from including in regulations requirements that previously had been applied as license conditions.

5.95 Therapy-related computer systems (§ 35.657).

The final rule adds a new § 35.657 requiring licensees to perform acceptance testing in accordance with published protocols accepted by nationally recognized bodies. Sections 35.657(a) through (e) specify the activities that the acceptance testing must include.

Cost Impacts: None anticipated. Licensees using computerized operating and planning systems currently verify their proper operation by conducting detailed acceptance testing.

Health and Safety Impacts: Acceptance testing and verification of correct operation ensure safe operation of these systems.

Benefits: Codifies existing practice.

5.96 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.690).

The current rule, in § 35.960, specifies the training requirements for the authorized user of a sealed source in a teletherapy unit.

Section 35.960(a) lists four specialist boards through which an individual may become certified to use sealed sources in a teletherapy unit.

Section 35.960(b) specifies training and experience requirements that may be met in lieu of certification by one of the four listed speciality boards. It currently requires 200 hours of classroom and laboratory training in specified subjects. In addition, it requires 500 hours of specific, supervised work experience. The current rule also requires 3 years of supervised clinical experience.

The final rule makes the following changes:

The list of four specialist boards is eliminated. Section 35.690 requires that, except as provided in § 35.57, the licensee shall require the authorized user of a sealed source for a use listed in § 35.600 to be a physician who is certified by a medical speciality board whose certification process includes all of the requirements in § 35.690(b) and whose certification has been recognized by the Commission or by an Agreement State.

Alternatively, § 35.690(b) provides that the physician must have completed a structured educational program in basic radionuclide techniques, including specified areas of training, applicable to the use of a sealed source in a therapeutic medical unit and must have completed 200 hours of classroom and laboratory training in specified topics and 500 hours of work experience, including specified activities, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution; and has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience. The physician also must have obtained written certification that the individual has satisfactorily completed the requirements in §§ 35.690(b)(1) and (b)(2) and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Cost Impacts: The cost impacts of the final rule apply to both NRC/Agreement States and licensees.

NRC estimates that approximately 150 physicians will seek to become authorized users under § 35.690 or equivalent Agreement State regulations annually. Of these, 95 percent, or 143, seek certification by a certifying board under § 35.690(a). No additional cost impacts be created for them under the final rule. NRC estimates that the remainder, or approximately seven physicians, seek to become authorized users under § 35.690(b). New costs for securing a preceptor statement are created by the final rule.

The costs to NRC/Agreement States for recognizing specialty boards for purposes of § 35.690(a) are estimated below. Because of the complexity of training under this section, NRC has assumed that medical boards that have sought recognition under other sections may prepare a separate application under this section.

Assumptions:

NRC/Agreement States: Number of boards: 3; NRC/Agreement States review time: 4 hours/board at $75 per hour; Total Cost Increase to NRC: $1,000.

Certifying boards incur costs for preparing a submission supporting their recognition.

Assumptions:

Certifying Boards: Number of boards reviewed: 3; Preparation of submission: 12 hours/board for Technical Staffat $30/hour; 4 hours/board for Management at $100/hour; Total Cost Increase for Certifying Boards: $2,000; Total Cost Increase for § 35.690(a): $3,000.

The costs to applicants associated with securing a preceptor's certification for purposes of § 35.690(b) are estimated below.

Assumptions:

Licensees: Number of candidates: 7; Cost per preceptor statement (½ hour of preceptor's time and ½ hour of candidate's time): $60; Total Cost Increase for § 35.690(b): <$1,000; Total Cost Increase for § 35.690: $3,000.

Health and Safety Impacts: None anticipated.

Benefits: Training and experience commensurate with risk and focused on radiation safety.

SUBPART I—[RESERVED]

SUBPART J—[RESERVED]

Subpart J of the current rule establishes training and experience requirements as follows: § 35.900 Radiation Safety Officer; § 35.901 Training for experienced Radiation Safety Officer; § 35.910 Training for uptake, dilution, and excretion studies; § 35.920 Training for imaging and localization studies; § 35.930 Training for therapeutic use of unsealed byproduct material; § 35.932 Training for treatment of hyperthyroidism; § 35.934 Training for treatment of thyroid carcinoma; § 35.940 Training for use of brachytherapy sources; § 35.941 Training for ophthalmic use of strontium–90; § 35.950 Training for use of sealed sources for diagnosis; § 35.960 Training for teletherapy; § 35.961 Training for teletherapy physicist; § 35.970 Training for experienced authorized users; § 35.971 Physician training in a three month program; § 35.972 Recentness of training; § 35.980 Training for authorized nuclear pharmacist; § 35.981 Training for experienced nuclear pharmacists.

The final rule eliminates Subpart J. Training and experience requirements in the final rule are in Subparts B and D through H of the final rule. The cost impacts, health and safety effects, and benefits of the training and experience requirements in the final rule are addressed under the relevant sections of the final rule.

SUBPART K—OTHER MEDICAL USES OF BYPRODUCT MATERIAL OR RADIATION FROM BYPRODUCT MATERIAL

5.97 Other medical uses of byproduct material or radiation from byproduct material (§ 35.1000).

The final rule, in new § 35.1000, provides that a licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in Subpart D through H of 10 CFR Part 35 if: (1) the applicant or licensee submits the information required by § § 35.12 (b) through (d); and (2) the applicant or licensee receives written approval from the Commission and uses the material in accordance with the regulations and specific conditions deemed necessary by the Commission for the medical use of the material.

Cost Impacts: Applicants for other medical uses will need to prepare and submit information as specified under § § 35.12 (b) through (d). However, the requirements under § 35.12(d) are an alternative to the requirements for an exemption under § 35.19 and are anticipated to provide cost savings. The cost savings are estimated under § 35.12(d).

Health and Safety Impacts: None anticipated.
Benefits: Regulatory efficiency, as a result of specification of requirements in advance.

SUBPART L—RECORDS

5.98 Records of authority and responsibilities for radiation protection programs (§ 35.2024).

Section 35.2024(a) requires licensees to retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years and specifies the contents of those records. Section 35.2024(b) requires licensees to retain a copy of both the authority, duties, and responsibilities of the Radiation Safety Officer, as required by § 35.24(e), and a signed copy of each RSO's written agreement, as required by § 35.24(b), for the duration of the license. Section 35.2024 requires the records to include the signature of the Radiation Safety Officer and licensee management.

Cost Impacts: The final rule reduces the record retention period for records of actions taken by licensee's management under § 35.24(a), which under the current rule lasts until the Commission terminates the license, to 5 years. Therefore, small cost reductions occur with shorter record retention periods.

Assumptions:

Licensees: Licensees: 5,793; Reduction in storage requirements: 1 cubic foot (about ½ file drawer); Cost of storage: $1.50 per cubic foot; Total Annual Cost Savings from § 35.2024: $9,000.

Health and Safety Impacts: None anticipated.
Benefits: Cost savings for licensees.

5.99 Records of radiation protection program changes (§ 35.2026).

The final rule, in new § 35.2026, provides that a licensee must retain a record of each radiation protection program change made in accordance with § 35.26(a), for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of licensee management that reviewed and approved the change.

Section 35.31(b) currently requires that a licensee retain a record of each "radiation safety program" change until the license has been renewed or terminated. Under the current rule, the record must include "the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative."

Section 35.26 of the final rule amends § 35.31(b) to eliminate the quoted requirements and provides that a licensee shall retain a record of each change in accordance with § 35.2026. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management who reviewed and approved the change.

Cost Impacts: Small cost reductions are expected with shorter record retention periods, as follows:

Assumptions:

Licensees: Total licensees: 5,793; Reduction in storage requirements: 2 cubic feet (about 1 file drawer); Cost of storage: $1.50 per cubic foot; Total Annual Cost Savings from § 35.2026: $17,000.

Health and Safety Impacts: None anticipated.
Benefits: Cost savings for licensees.

5.100 Records of written directives (§ 35.2040).

The final rule, in new § 35.2040, requires licensees to retain a copy of the written directive, as required by § 35.40, for 3 years.

Cost Impacts: Because the number of procedures requiring written directives is not expected to change under the requirements of § 35.40 of the final rule, the scope of the recordkeeping requirements under § 35.2040 of the final rule is not expected to change. The final rule requires a 3-year record retention period, which corresponds to the record retention period for written directives under the current rule. Therefore, no cost impacts are anticipated.

Health and Safety Impacts: None anticipated.
Benefits: Conforming change.

5.101 Records for procedures for administrations requiring a written directive (§ 35.2041).

The final rule, in new § 35.2041, requires licensees to retain a copy of the procedures for administrations requiring a written directive, as required by § 35.41(a), for the duration of the license.

Cost Impacts: No cost impacts are anticipated. The requirement in § 35.2041 to retain a copy of these procedures does not differ from the current need to retain a copy of the quality management program, which is implicitly included in the requirement in the current § 35.32(a) to "maintain" a quality management program.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.102 Records of calibrations of instruments used to measure the activity of unsealed byproduct material (§ 35.2060).

The final rule, in new § 35.2060, requires a licensee to maintain a record of instrument calibrations required by § 35.60 for 3 years and specifies that the records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

The final rule uses the phrase "instrument calibrations." Therefore, the scope of the final rule potentially is increased, through the inclusion of records of calibrations of instruments in addition to dose calibrators.

Cost Impacts: The final rule is anticipated to result in minimal (<$1,000) increased recordkeeping costs.

Health and Safety Impacts: None anticipated.

Benefits: The calibration ensures that instruments are functioning correctly and establishes trends in equipment performance.

5.103 Records of radiation survey instrument calibrations (§ 35.2061).

The final rule, in new § 35.2061, requires a licensee to maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years and specifies the contents of that record.

Cost Impacts: The final rule duplicates the recordkeeping requirements in § 35.51(d) of the current rule. The record retention period remains 3 years. Therefore, no cost impacts are anticipated from the final rule.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.104 Records of dosages of unsealed byproduct material for medical use (§ 35.2063).

The final rule, in new § 35.2063, requires a licensee to maintain a record of dosage determinations required by § 35.63 for 3 years and specifies the records that must be maintained.

The recordkeeping requirements in the final rule parallel the recordkeeping requirements in § 35.53 of the current rule. The record retention period remains 3 years. The final rule makes two changes: (1) eliminating the requirement that the record contain the expiration dates of the radiopharmaceutical; and (2) changing "measurements" to "determination" in § 35.2063(b)(3) of the final rule.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.105 Records of leak tests and inventory of sealed sources and brachytherapy sources (§ 35.2067).

The final rule, in new § 35.2067(a), requires records of leak tests of sealed sources and brachytherapy sources required by § 35.67(b) of the final rule to be retained for 3 years and specifies the contents of the records. Section 35.2067(b) requires records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) of the final rule to be retained for 3 years and specifies the content of the inventory records.

Cost Impacts: The final rule duplicates, with one change, the recordkeeping requirements in §§ 35.59(d) and (g) of the current rule. The final rule reduces the record retention time from 5 years to 3 years. This reduction of the record retention period by 2 years is expected to result in small cost savings to licensees, as follows:

Assumptions:

Licensees: Licensees: 1,876; Reduction in storage requirements: 1 cubic foot (about ½ file drawer); Cost of storage: $1.50 per cubic foot; Total Annual Cost Savings from § 35.2067: $3,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings for licensees.

5.106 Records of surveys for ambient radiation exposure rate (§ 35.2070).

The final rule, in new § 35.2070, requires licensees to retain a record of each survey required by § 35.70 for 3 years. The final rule parallels the recordkeeping requirements in § 35.70(h) of the current rule.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.107 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material (§ 35.2075).

The final rule, in new § 35.2075(a), requires a licensee to retain a record of the basis for authorizing the release of an individual in accordance with § 35.75 if certain specified calculations were used. Section 35.2075(b) requires that a record be retained that the instructions required by § 35.75(b) were provided to a breast feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5mSv (0.5 rem). Section 35.2075(c) requires licensees to retain records of patient release required by § § 35.75(a) and (b) for 3 years after the date of release of the individual.

Cost Impacts: None anticipated. The recordkeeping requirements in the final rule parallel the recordkeeping requirements in § § 35.75(c) and (d) of the current rule. Therefore, no incremental costs or cost savings are anticipated from the final rule.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.108 Records of mobile medical services (§ 35.2080).

The final rule, in new § 35.2080, requires licensees to retain a copy of the letter(s) that permit the use of byproduct material at a client's address of use, in accordance with § 35.80(a)(l), for 3 years after the provision of last service. Section 35.2080(a) also requires the letter to clearly delineate the authority and responsibility of each entity. Section 35.2080(b) requires licensees to retain a record of each survey required by § 35.80(a)(4) for 3 years and specifies the contents of the records.

Cost Impacts: None anticipated. The recordkeeping required in § 35.2080 of the final rule is also required in § 35.80(f) of the current rule. Therefore, no incremental costs or cost savings are anticipated from the final rule.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.109 Records of decay-in-storage (§ 35.2092).

The final rule, in new § 35.2092, requires a licensee to maintain records of the disposal of licensed materials by decay in storage as permitted by § 35.92 for 3 years. The record must include: the date of the disposal; the survey instrument used; the background radiation level; the radiation level measured at the surface of each waste container; and the name of the individual who performed the survey.

Cost Impacts: The final rule parallels, with one change, the recordkeeping requirements in § 35.92 of the current rule. The final rule eliminates the requirement that the record include the date on which the byproduct material was placed in storage. Therefore, the final rule may create small cost savings (i.e., <$1,000) for licensees, as a result of the slight reduction in the scope of records that must be maintained.

Health and Safety Impacts: None anticipated.

Benefits: Small cost savings for licensees (<$1,000).

5.110 Records of molybdenum–99 concentrations (§ 35.2204).

The final rule, in new § 35.2204, requires licensees to maintain a record of the molybdenum–99 concentration tests required by § 35.204(b) for 3 years and specifies the contents of the record.

Cost Impacts: The final rule parallels, with changes, the recordkeeping requirements in the current rule in § 35.204(c). The changes in § 35.204 reduce the number of required measurements, thus reducing the number of records that must be maintained.

Cost savings to licensees are estimated at:

Assumptions:

Licensees: Total licensees: 2,069; Reduction in storage requirements: 4 cubic feet (about 2 file drawers); Cost of storage: $1.50 per cubic foot; Total Annual Cost Savings from § 35.2204: $12,000.

Health and Safety Impacts: None anticipated.

Benefits: Cost savings for licensees.

5.111 Records of safety instruction (§ 35.2310).

The final rule, in new § 35.2310, requires a licensee to maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include: a list of topics covered; the date of the instruction; the name(s) of the attendee(s); and the name(s) of the individual(s) who provided the instruction.

The final rule parallels, with one change, the recordkeeping requirements in the current rule in §§ 35.310(b), 35.410(b), and 35.610(c). The final rule eliminates the requirement that the record include a description of the instruction. Therefore, the final rule creates small cost savings (i.e., <$1,000) for licensees using unsealed byproduct material for therapeutic administration, manual brachytherapy, and teletherapy. However, §§ 35.310, 35.410, and 35.610 are amended to require radiation safety instruction "initially and at least annually." Such annual training, and records of such training, previously has been required by license condition.

Cost Impacts: Small cost savings are anticipated (<$1,000).

Health and Safety Impacts: None anticipated.

Benefits: Small cost savings to licensees.

5.112 Records of surveys after source implant and removal (§ 35.2404).

The final rule, in new § 35.2404, requires that a licensee maintain a record of the radiation surveys required by §§ 35.404 and 35.604 for 3 years and specifies that each record must contain the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

The final rule slightly reduces the scope of the records that must be maintained, because licensees for manual brachytherapy are not required to maintain a record of the dose rate from the patient or human research subject, as currently required by § 35.404(b).

Cost Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.113 Records of brachytherapy source accountability (§ 35.2406).

The final rule, in new § 35.2406, requires licensees to maintain a record of brachytherapy source accountability required by § 35.406 for 3 years and specifies the records that must be maintained.

The final rule reorganizes and reduces the recordkeeping requirements in § 35.406 of the current rule. The record retention period does not change.

Section 35.2406(b), which parallels the requirements in the current rule in § 35.406(b), with changes, specifies requirements for records of temporary implants. However, it eliminates the requirement to maintain a record of the name of the individual permitted to handle the sources; the requirement to record the name and room number of the patient or human research subject; and the number and activity of sources in storage after the return of sources after removal from a patient or human research subject.

Section 35.2406(c), a new paragraph, specifies requirements for records of permanent implants. It requires the record to include the number and activity of sources removed from storage and the name of the individual who removed them from storage; the date they were removed from storage; the number and activity of sources not implanted; the date they were returned to storage and the name of the individual who returned them to storage; and the number and activity of sources permanently implanted in the patient or human research subject.

The final rule is not expected to increase the scope of the records that must be maintained, because records of inventory for brachytherapy sources used for permanent implants are covered, under the current rule. The final rule is expected to result in small cost savings (i.e., <$1,000) for licensees from the reduced scope of the inventory records that must be maintained.

Cost Impacts: Small cost savings to licensees (<$1,000).

Health and Safety Impacts: None anticipated.

Benefits: Cost savings to licensees.

5.114 Records of calibration measurements of brachytherapy sources (§ 35.2432).

The final rule, in new § 35.2432, requires a licensee to maintain a record of the calibrations on brachytherapy sources required by § 35.432 for 3 years after the last use of the source. The final rule specifies that the record must include: the date of the calibration; the manufacturer's name, the model number, and serial number for the source and instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

Cost Impacts: The current rule contains no requirements pertaining to records of full calibrations on brachytherapy sources. Therefore, this section of the final rule creates small (i.e., <$1,000), new cost impacts for licensees.

Health and Safety Impacts: Increased safety.

Benefits: Conforming change.

5.115 Records of decay of strontium–90 sources for ophthalmic treatments (§ 35.2433).

The final rule, in new § 35.2433, requires a licensee to maintain a record of the activity of a strontium–90 source required by § 35.433 for the life of source. The final rule specifies that the record must include the date and the initial activity of the source as determined under § 35.432; and for each decay calculation, the date and source activity as determined under § 35.433.

Cost Impacts: The current rule contains no requirements pertaining to records of decay for strontium–90 sources used for ophthalmic treatments. Therefore, this section of the final rule creates small (i.e., <$1,000), new cost impacts for licensees.

Health and Safety Impacts: Increased safety.

Benefits: Conforming change.

5.116 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.2605).

The final rule, in new § 35.2605, requires that a licensee retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years and specifies that for each installation, maintenance, adjustment, and repair, the record must include: the date; description of the service; and name(s) of the individual(s) who performed the work.

Cost Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change resulting from the restructuring of 10 CFR Part 35.

5.117 Records of safety procedures (§ 35.2610).

The final rule, in new § 35.2610, requires that a licensee retain a record of the procedures required by § 35.610(a)(4) for responding to abnormal situations for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, and retain a record of the operating procedures for the unit(s) required by § 35.610(d)(2), until the licensee no longer possesses the unit(s).

Impacts: None anticipated. These requirements are implicit in §§ 35.610(a)(4) and (d)(2).

Health and Safety Impacts: None anticipated.

Benefits: Regulatory clarity and efficiency. Without this explicit statement, licensees would have had to reference the general recordkeeping provisions of § 30.51(b) and therefore, would have had to retain these procedures for the duration of the license.

5.118 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.2630).

The final rule, in new § 35.2630, requires that a licensee retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license and specifies in detail what information must be included in each of these records.

Cost Impacts: The final rule parallels the recordkeeping requirements in the current rule in § 35.630. However, the final rule eliminates the requirement for evidence to be provided that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM. Therefore, this section of the final rule creates no new cost impacts for licensees.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.119 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations (§ 35.2632).

The final rule, in new § 35.2632, requires that a licensee maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years and specifies in detail what information must be included in each of these records.

The final rule parallels, with three exceptions, the recordkeeping requirements in the current rule in § 35.632(g). The final rule changes the record retention period

from the duration of use of the teletherapy source to 3 years after the last use of the source. It does not require maintenance of a record of the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit. It refers to the "authorized medical physicist" instead of the "teletherapy" physicist, to conform to the nomenclature of the final rule.

Cost Impacts: This section of the final rule creates small incremental costs (i.e., <$1,000) for licensees as a result of the increase in the length of the record retention period.

Health and Safety Impacts: None anticipated. Records already being retained.

Benefits: Demonstrates that calibrations were done correctly and correct doses administered. Conforming change to restructuring of 10 CFR Part 35.

5.120 Records of periodic spot-checks for teletherapy units (§ 35.2642).

The final rule, in new § 35.2642, requires that a licensee retain a record of each periodic spot-check for teletherapy units, required by § 35.642(a) for 3 years; and a copy of the procedures for performing spot-checks established by the authorized medical physicist, required by § 35.642(b), until the licensee no longer possesses the unit. The final rule also specifies in detail what information must be contained in the records of the spot-checks.

The final rule parallels, with minor changes, the recordkeeping requirements for periodic spot-checks for teletherapy units in the current rule in § 35.634(f).

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.121 Records of periodic spot-checks for remote afterloader units (§ 35.2643).

The final rule, in new § 35.2643, requires that a licensee retain a record of each spot-check for remote afterloaders, required by § 35.643(a), for 3 years; and retain a copy of the procedures for performing spot-checks establish by the authorized medical physicist, required by § 35.643(b), until the licensee no longer possesses the unit. The final rule also specifies in detail what information must be contained in the record of each spot-check.

Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.122 Records of periodic spot-checks for gamma stereotactic radiosurgery units (§ 35.2645).

The final rule, in new § 35.2645, requires that a licensee retain a record of each spot-check for gamma stereotactic radiosurgery units, required by § § 35.645(c) and (d), for 3 years; and a record of the procedures for performing the spot-checks established by the authorized medical physicist, required by § 35.645(b), until the licensee no longer possesses the unit. The final rule also specifies in detail what information must be contained in the records of each spot-check.

Cost Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.123 Records of additional technical requirements for mobile remote afterloader units (§ 35.2647).

The final rule, in new § 35.2647, requires that a licensee retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years. The final rule also specifies in detail what information must be contained in each of these records.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

5.124 Records of surveys of therapeutic treatment units (§ 35.2652).

The final rule, in new § 35.2652, requires that a licensee maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit and specifies in detail what information must be included in the record.

The final rule parallels, with changes, the requirements for records of radiation surveys for teletherapy facilities in § 35.641 of the current rule. The final rule requires records to be maintained for the duration of use of the unit, rather than for the duration of the license. It does not require a record to be maintained for why

the survey is required; a plan of the areas surrounding the treatment room that will be surveyed; the measured dose rate at several points in each area, or the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area. This section of the final rules reduce the cost impacts for licensees of teletherapy sources. The final rule also creates a new regulatory requirement for other therapy units. However, the net effect is anticipated to be small (i.e., <$1,000).

Cost Impacts: None anticipated. The requirements are consistent with current license conditions.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

5.125 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units (§ 35.2655).

The final rule, in new § 35.2655, requires that a licensee maintain a record of the 5-year inspection for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit and specifies in detail what information the record must contain.

The final rule parallels, with changes, the requirements for 5-year inspections of teletherapy units in § 35.647 of the current rule. The costs of conducting the inspections are estimated under its replacement, § 35.655 of the final rule. The final rule requires records to be maintained for the duration of use of the unit, rather than for the duration of the license. It does not require a record to be maintained of the list of components replaced, which lessens the cost impacts for licensees of teletherapy sources.

Cost Impacts: The current rule does not contain requirements for records of 5-year inspections for gamma stereotactic radiosurgery units. A cost increase is anticipated, as follows:

Assumptions:

Licensees: Total licensees: 53; Increase in storage requirements: 2 cubic feet (about 1 file drawer); Cost of storage: $1.50 per cubic foot; Total Annual Cost Increase from § 35.2655: <$1,000.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change.

SUBPART M

5.126 Report and notification of a medical event (§ 35.3045).

Section 35.3045(a) requires a licensee to report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material, results in a dose meeting or exceeding specified criteria in §§ 35.3045(a)(1), (2), or (3). This reporting requirement is needed to ensure that NRC is aware of medical events and to promptly take any necessary actions based on the circumstances.

Section 35.3045(b) requires a licensee to report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician

Section 35.3045(c) requires licensees to notify the NRC Operations Center by telephone no later than the next calendar day after discovery of the medical event.

Section 35.3045(d) requires licensees to submit a written report to the appropriate NRC Regional Office within 15 days after the discovery of the medical event. The report must include: the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect, if any, on the individual(s) who received the administration; what actions, if any, have been taken or are planned to prevent recurrence; certification that the licensee notified the individual (or the individual's responsible relative or guardian); and if not, why not. The report must not contain the individual's name or any other information that could lead to identification of the individual. This reporting requirement is needed to provide NRC a synopsis of the event, its cause(s), and corrective actions taken, so that NRC can ensure that appropriate follow-up actions are taken after medical events, and so that NRC can promptly notify other licensees if it appears the event might be generic.

Section 35.3045(e) requires the licensee to provide notification of the event to the referring physician and the individual who is the subject of the medical event, or that individual's responsible relative or guardian, no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that

he or she will inform the individual or that, based on medical judgment, telling the individual be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. If a verbal notification is made, the licensee is required to inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee then must provide such a written description if requested. Individuals and their referring physician(s) need this information to make timely decisions regarding possible health care needs.

Section 35.3045(f) specifies that aside from the notification requirement, nothing in § 35.3045 affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individuals responsible relatives or guardians.

Section 35.3045(g) provides that a licensee shall annotate a copy of the report provided to the NRC with the name of the individual who is subject to the event, and their social security number or other identification number, if one has been assigned. The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days after discovery of the medical event.

Cost Impacts: None anticipated. The changes in § 35.3045 of the final rule are not expected to substantially change the number or type of medical events to be reported under § 35.3045 from the number and type of misadministrations reported under the current rule. The deletion of the requirement to maintain a record of the misadministration (medical event) is not expected to have a significant cost impact because a report still needs to be prepared and sent to the NRC and to the referring physician.

Health and Safety Impacts: None anticipated.

Benefits: Reduced prescriptiveness as to providing written report or description of the medical event to the individual verbally notified.

5.127 Report and notification of a dose to an embryo/fetus or a nursing child (§ 35.3047).

Section 35.3047(a) requires the licensee to report to NRC any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is the result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to embryo/fetus was specifically approved, in advance, by the authorized user.

Section 35.3047(b) requires the licensee to report to NRC any dose to a nursing child that is the result of an administration of byproduct material to a breast-feeding individual that is greater than 50 mSv (5 rem) total effective dose equivalent or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician. This report is needed so that NRC can comply with the legislative intent of Section 208 of the Energy Reorganization Act of 1974 (P.L.93–438) as amended, which requires NRC to submit reports of unintended radiation exposure to Congress.

Section 35.3047(c) requires the licensee to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report under §§ 35.3047(a) or (b). This reporting requirement is needed to ensure that NRC is aware of unintended radiation exposure to an embryo/fetus or nursing child and can promptly take any necessary actions based on the circumstances.

Section 35.3047(d) requires the licensee to submit a written report to the appropriate NRC Regional Office within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report under §§ 35.3047(a) or (b). The written report must include: the licensee's name; the name of the prescribing physician; a brief description of the event; why the event occurred; the effect, if any, on the embryo/fetus or nursing child; what actions, if any, have been taken or are planned to prevent recurrence; and certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child. This reporting requirement is needed to provide information to NRC about the causes of the unintended radiation exposure to an embryo/fetus or nursing child and methods to prevent recurrence.

Section 35.3047(e) requires the licensee to provide notification of the event to the referring physician and also notify the pregnant individual or mother no later than 24 hours after discovery of an event that requires reporting under paragraph (a) or

(b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother, or that, based on medical judgment, telling the mother be harmful. The licensee is not required to notify the mother without first consulting the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. The licensee can demonstrate compliance with this paragraph by notifying the mother's or child's responsible relative or guardian. If a verbal notification is made, the licensee is required to inform the mother, or the mother's or child's responsible relative or guardian, instead of the mother, that a written description of the event can be obtained from the licensee upon request. The licensee then must make such a written description available if requested.

Section 35.3047(f) provides that a licensee shall annotate a copy of the report provided to the NRC with the name of the individual who is subject to the event, and their social security number or other identification number, if one has been assigned. The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, within 15 days after discovery of the medical event.

Cost Impacts: Cost increases are anticipated from requirements in § 35.3047(a) that require licensees to report a dose to an embryo/fetus and requirements in § 35.3047(b) that require licensees to report a dose to a nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees. Costs are addressed under § § 35.3047(c) and (d).

Cost increases are anticipated from requirements in § 35.3047(c) that require licensees to notify by phone the NRC Operation Center within five days after discovery of a dose to an embryo/fetus or nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees.

Assumptions:

Licensees: Total annual reports: 10; Total phone reporting time, hours: 0.5; Technical staff hourly rate: $30; Total Annual Cost Increase for licensees from § 35.3047(c): <$1,000.

Cost increases are anticipated from requirements in § 35.3047(d) that require licensees to submit a written report to the appropriate NRC Regional Office within 30 days after discovery of a dose to the embryo/fetus or nursing child. NRC anticipates that 10 such administrations occur annually for NRC and Agreement States licensees.

Assumptions:

Licensees: Total annual licensee administrations: 10; Total report preparation time, hours: 8; Technical staff hourly rate: $30; Total Annual Cost Increase for licensees from § 35.3047(d): $2,000.

Cost increases are anticipated from requirements in § § 35.3047(e) and (f) that require notification to the referring physician and also to the mother. NRC anticipates that 10 such notifications occur annually for NRC and Agreement States licensees.

Assumptions:

Licensees: Total annual licensee notifications: 10; Total notification time, hours: 2.5; Technical staff hourly rate: $30; Total Annual Cost Increase for licensees from § § 35.3047(e) and (f): $1,000; Total Annual Cost Increase for licensees from § 35.3047: $4,000.

Health and Safety Impacts: Provides notification of such events to individual and to referring physician.

Benefits: Provides NRC with information to comply with Section 208 of the Energy Reorganization Act and to determine the nature and frequency of such events.

5.128 Report of a leaking source (§ 35.3067).

This section requires that licensees file a written report within five days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 microcurie) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC. The report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken. This report enables NRC to promptly determine if the necessary follow-up actions are necessary following discovery of the leaking source.

Cost Impacts: None anticipated.

Health and Safety Impacts: No health and safety impacts are anticipated.

Benefits: Conforming change.

SUBPART N—ENFORCEMENT

The final rule amends the former Subpart K and retitles it as Subpart N and makes the following changes:

5.129 Violations (§ 35.4001).

Section 35.990 of the current rule specifies that the Commission may obtain an injunction or other court order to prevent specified violations.

The final rule renumbers § 35.990 as new § 35.4001, without other changes.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

5.130 Criminal penalties (§ 35.4002).

Section 35.991(a) of the current rule specifies that the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, or attempted violation of, or conspiracy to violate, any regulation issued under specified sections of the Act. Section 35.991(b) lists the regulatory sections that are not covered by criminal sanctions.

The final rule renumbers § 35.991 as § 35.4002 and makes conforming changes to the section numbers in the final rule.

Cost Impacts: None anticipated.

Health and Safety Impacts: None anticipated.

Benefits: Conforming change to restructuring of 10 CFR Part 35.

5.131 Dose limits for individual members of the public (10 CFR 20.1301).

10 CFR 20.1301(a) of the current rule provides that each licensee shall conduct operations so that certain dose limits are maintained for members of the public.

The final rule amends 10 CFR 20.1301(a) to add a new paragraph, 20.1301(c), that provides that, notwithstanding the requirements in paragraph (a)(1), a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than (1 mSv) 0.1 rem, but not to exceed (5 mSv) 0.5 rem, if the authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate .

The final rule addresses a Petition for Rulemaking (PRM–20–24) dated April 7, 1996, from the University of Cincinnati. On June 21, 1996 (61 FR 31874), the NRC published a notice of receipt and a request for comment on the petition (PRM–20–24). All commenters agreed with the petitioner that it was unreasonable to require licensees to limit doses to specified visitors to the public dose limit of 1 mSv (0.1 rem). A draft rulemaking plan was prepared and provided to the Agreement States on May 1, 1997, for review and comment, and a final rulemaking plan was submitted to the Commission for approval on August 1, 1997. The NRC determined that the following alternatives should be evaluated:

• *Alternative 1: retain the 1 mSv (0.1 rem) public dose limit*

This alternative evaluates the cost effectiveness of retaining the current dose limit of 1 mSv (0.1 rem) to an individual exposed to a hospitalized radiation patient. The petition would be denied on the basis that there are sufficient provisions within 10 CFR 20.1301(c) to allow case-by-case use of the 5 mSv (0.5 rem) annual dose limit for visitors of radiation patients.

• *Alternative 2: 5 mSv (0.5 rem) public dose limit for specified visitors of radiation therapy patients*

This alternative incorporates the provisions requested by the petitioner and evaluates the cost effectiveness of amending 10 CFR 20.1301 to permit, on a case-by-case basis, consenting adult, nonpregnant visitors to receive up to 5 mSv (0.5 rem) in a year from exposure to radiation therapy patients and to direct the authorized user to provide basic radiation safety instruction to visitors to minimize their doses while visiting the patient and require licensees to badge those visitors whose total effective dose equivalent exceed 1 mSv (0.1 rem).

• *Alternative 3: 5 mSv (0.5 rem) public dose limit for visitors of radiation patients without badging or recordkeeping*

This alternative evaluates the cost effectiveness of amending 10 CFR 20.1301 to permit visitors to individuals who are not released in accordance with § 35.75 to receive a radiation dose greater than 1 mSv (0.1 rem) but not to exceed 5 mSv (0.5 rem) if the authorized user determines that it is appropriate. No visitor badging or recordkeeping would be required in this alternative.

Cost Impacts: Costs of safety instructions: Alternatives 1 and 3 have no requirement for providing ALARA instructions to either the hospitalized patient or the vis-

itor to the radiation patient and therefore have no related cost. However, the final rule associated with Alternative 2 would impose additional costs for providing basic radiation safety instruction to the 4,650 patients and 9,300 visitors. A cost of $22 per radiation patient or $102.3 thousand per year is the estimated total cost of providing instruction for Alternative 2. This estimate, obtained from NUREG–1492 (NRC 1997), assumes that the licensee spends 10 minutes providing instruction to the patient and visitors.

Costs of recordkeeping: Alternatives 1 and 3 have no recordkeeping requirements and therefore have no related costs. However, the final rule associated with Alternative 2 would impose additional paperwork and recordkeeping requirements on the estimated 1,350 licensees (NRC- and Agreement States-licensed) that provide therapeutic administrations of radiopharmaceuticals to hospitalized patients. A record documenting the receipt of informed consent from the visitor to potentially receive up to the 5 mSv (0.5 rem) dose limit, receipt of basic safety instruction, and external radiation dosimetry records must be maintained for 3 years. It is estimated that approximately 4,650 procedures per year would be subject to these requirements. A cost of $17 per radiation patient or $79.1 thousand per year is the estimated total cost for record keeping. This estimate, obtained from NUREG–1492 (NRC 1997), assumes that the licensee spend 8 minutes per patient documenting the provisions of instruction and dosimetric monitoring.

Costs of Providing Dosimetry: Alternatives 1 and 3 have no dosimetry requirements, and therefore, have no related costs. However, the final rule associated with Alternative 2 would impose new dosimetry and paperwork requirements on the estimated 1,350 licensees (NRC- and Agreement States-licensed) that provide diagnostic and therapeutic administrations of radiopharmaceuticals to hospitalized patients. The cost of the dosimeter and dosimeter processing is estimated at $2.50 each. Labor associated with TLD or film badge issuance to and return from the visitor, and badge receipt from and shipment to a NVLAP accredited processing contractor is estimated at $14.00. A cost of $16.50 per visitor is estimated. This results in an annual estimated cost of approximately $153,400.

Qualitative Benefits: Retention of patients in a hospital by design necessitates that the patient be "isolated" and that human contact, inclusive of family members, is either minimized or avoided. This isolation may bring about numerous changes and impositions in the lives of the patient and family members. The deterioration in the quality of life brought on by illness is frequently referred to as an "intangible cost." For thyroid cancer or thyroid dysfunction requiring therapeutic doses of I–131, for example, a deterioration in the quality of life may be precipitated by the loss of bodily function, a lifetime dependence on medication, hormonal instability, uncertainty of normal life-expectancy, disruption of normal daily routines, and reduced financial security related to employment, lost earnings, and medical expenses.

While some of these elements of intangible costs are the result of the disease itself, others such as disruption of normal routines, social isolation, and enhanced financial strain are clearly elements of psychological costs that are directly related to patient retention. Allowing greater visitor access to the patient while they are under licensee control will provide an unquantifiable amount of physical and emotional benefit to the patient and the visitor alike. However, the conversion of this benefit into an equivalent dollar amount is complex, highly subjective, and dependent upon the individual situation. Instead, this analysis uses a qualitative and reasonable approach to scope the range of possible responses.

Health and Safety: Selection of the 5 mSv (0.5 rem) total effective dose equivalent per year criterion is consistent with: (1) the Commission's provision in 10 CFR 20.1301(c) for authorizing a licensee to operate up to this limit; (2) the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection"; (3) the recommendations of the NCRP in NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation"; and (4) the International Atomic Energy Agency (IAEA) in Safety Series No. 115, "International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources." Each of these documents provides a basis for allowing visitors to radiation patients to receive annual doses up to 5 mSv (0.5 rem).

The ICRP recommends that dose limits should not be applied to medical exposures, if the medical exposure is intended to provide a direct benefit to the exposed individual and the dose is kept as low as is compatible with the medical purposes. In this instance, medical exposure is defined to include "exposures incurred by individuals as part of their own medical diagnosis and treatment and to exposures (other than occupational) incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis and treatment."

Current NCRP guidance regarding radiation protection dose limits (NCRP Report No. 116) recommends that any activity which involves radiation exposure must be justified on the basis of the expected benefits to society exceeding the overall cost, the total societal detriment is maintained ALARA, economic and social factors are taken into account, and individual dose limits are applied to ensure that the procedures of ALARA and justification do not result in individuals exceeding levels of acceptable risk. Based upon this basic radiation protection philosophy, NCRP Commentary 11 (1995), "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," noted that members of a radionuclide therapy patient's family are likely to perceive that the visitors also will benefit from providing emotional and physical support to the patient during their treatment, and these visitors are likely to be willing to bear greater risk in order to achieve that benefit. Consequently, the NCRP Commentary No. 11 recommends that the dose limit for adult family members [18] "exposed to a radionuclide therapy patient should not exceed 50 mSv annually. When family members are likely to receive exposures in excess of 5 mSv annually, they should receive appropriate training and individual monitoring."

The IAEA description of dose limits for individual members of the general public is similar to the recommendations of the ICRP and NCRP. IAEA–115 specifies that:

> II–9. The dose limits set out in this part shall not apply to comforters or patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients. However, the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of the patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv.

Preferred Alternative: To determine the preferred alternative, the costs and benefits that result when Alternatives 2 and 3 are each compared with Alternative 1 (the status quo) were analyzed. Both Alternatives 2 and 3 allow greater visitor access to the radiation patient, hence a larger collective dose is associated with these alternatives. Any potential detriment associated with this additional collective dose is offset by the qualitative benefit the patient and visitor receive under Alternatives 2 and 3. No monetary value was placed upon the qualitative benefit to either the patient or the specified visitor under each alternative. However, a net cost is associated with Alternative 2 to provide visitor badging, instruction and recordkeeping. No such requirements are associated with Alternative 3. The net cost of Alternative 2, compared to Alternatives 1 or 3, is anticipated to be $334,800. Evaluating the costs associated with monitoring individuals versus the benefits at these low doses, required monitoring is not considered to be justified, although the licensee is not precluded from monitoring and recording individual doses.

6. COSTS AND BENEFITS FOR ALTERNATIVES FOR REVISIONS TO 10 CFR PART 35

6.1 Summary of Estimated Annual Costs of Rule

Table 6–1 presents a summary of the estimated values and impacts of the revisions to 10 CFR Part 35. For each regulatory change described above, Table 6–1 lists the estimated total costs avoided (-) or total costs added (+) (i.e., the change in costs from the current rule) for that section.

Table 6–1.—Summary of the Rule's Cost Effects

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
A	35.1	0	0	0
	35.2	0	0	0
	35.5	0	0	0
	35.6	0	0	0
	35.7	0	0	0
	35.8	0	0	0

[18] NCRP Commentary No. 11 defines family member as "any person who spends a substantial amount of time in the company of the patient on a regular basis, providing support and comfort, and whom the patient considers a member of their 'family,' whether by birth, by marriage, or by virtue of a close, caring relationship."

Table 6–1.—Summary of the Rule's Cost Effects

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
	35.10	0	0	0
	35.11	0	0	0
	35.12	-1,000	0	–1,000
	35.13	-85,000	-81,000	–166,000
	35.14	10,000	12,000	22,000
	35.15	0	0	0
	35.18	0	0	0
B	35.20	0	0	0
	35.21	0	0	0
	35.22	0	0	0
	35.23	0	0	0
	35.24	-2,167,000	0	-2,167,000
	35.26	-14,000	0	-14,000
	35.27	-1,158,000	0	-1,158,000
	35.29	0	0	0
	35.32	-4,436,000	-1,899,000	-6,335,000
	35.33	0	0	0
	35.40	0	0	0
	35.41	0	0	0
	35.49	0	0	0
	35.50	5,000	2,000	7,000
	35.51	2,000	1,000	3,000
	35.55	2,000	1,000	3,000
	35.57	0	0	0
	35.59	0	0	0
C	35.60	-521,000	0	-521,000
	35.61	-136,000	0	-136,000
	35.63	0	0	0
	35.65	-5,000	-11,000	-16,000
	35.67	-56,000	0	-56,000
	35.69	0	0	0
	35.70	0	0	0
	35.75	0	0	0
	35.80	0	0	0
	35.90	0	0	0
	35.92	-1,000	-1,000	-2,000
D	35.100	0	0	0
	35.120	0	0	0
	35.190	5,000	2,000	7,000
	35.200	0	0	0
	35.204	-993,000	0	-993,000
	35.205	0	0	0
	35.220	0	0	0
	35.290	-238,000	0	-238,000
E	35.300	0	0	0
	35.310	0	0	0
	35.315	0	0	0
	35.320	0	0	0
	35.390	63,000	0	63,000
	35.392	3,000	1,000	4,000
	35.394	0	0	0
F	35.400	-2,000	-2,000	-4,000
	35.404	-2,000	-3,000	-5,000
	35.406	0	0	0
	35.410	0	0	0
	35.415	0	0	0

Table 6–1.—Summary of the Rule's Cost Effects

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
	35.420	0	0	0
	35.432	748,000	0	748,000
	35.433	364,000	0	364,000
	35.457	0	0	0
	35.490	0	1,000	1,000
	35.491	1,000	0	1,000
G	35.500	-1,000	-1,000	-2,000
	35.520	0	0	0
	35.590	0	0	0
H	35.600	0	0	0
	35.604	0	0	0
	35.605	0	0	0
	35.606	0	0	0
	35.610	0	0	0
	35.615	-187,000	0	-187,000
	35.620	0	0	0
	35.630	0	0	0
	35.632	0	0	0
	35.633	0	0	0
	35.635	0	0	0
	35.636	0	0	0
	35.641	0	0	0
	35.642	0	0	0
	35.643	0	0	0
	35.645	-1,000	0	-1,000
	35.647	0	0	0
	35.652	0	0	0
	35.655	0	0	0
	35.657	0	0	0
	35.690	2,000	1,000	3,000
J	35.900	0	0	0
	35.910	0	0	0
	35.920	0	0	0
	35.930	0	0	0
	35.932	0	0	0
	35.934	0	0	0
	35.940	0	0	0
	35.941	0	0	0
	35.950	0	0	0
	35.960	0	0	0
	35.961	0	0	0
	35.980	0	0	0
K	35.1000	0	0	0
L	35.2024	-9,000	0	-9,000
	35.2026	-17,000	0	-17,000
	35.2040	0	0	0
	35.2060	0	0	0
	35.2061	0	0	0
	35.2063	0	0	0
	35.2067	-3,000	0	-3,000
	35.2070	0	0	0
	35.2075	0	0	0
	35.2080	0	0	0
	35.2092	0	0	0
	35.2204	-12,000	0	-12,000
	35.2310	0	0	0

Table 6–1.—Summary of the Rule's Cost Effects

Subpart	Section	Change in Licensee Costs (nominal $)	Change in NRC and Agreement States Costs (nominal $)	Total Change in Costs (nominal $)
	35.2401	0	0	0
	35.2404	0	0	0
	35.2406	0	0	0
	35.2432	0	0	0
	35.2433	0	0	0
	35.2605	0	0	0
	35.2610	0	0	0
	35.2630	0	0	0
	35.2632	0	0	0
	35.2642	0	0	0
	35.2643	0	0	0
	35.2645	0	0	0
	35.2647	0	0	0
	35.2652	0	0	0
	35.2655	0	0	0
M	35.3045	0	0	0
	35.3047	4,000	0	4,000
	35.3067	0	0	0
N	35.4001	0	0	0
	35.4002	0	0	0
10 CFR 20.1301	Alt. 3	0	0	0
Total Cost Savings		$8,836,000	$1,977,000	$10,813,000

6.2 Estimated Lifetime Costs of Rule

NRC estimates the revisions to 10 CFR Part 35 will result in total annual cost savings of $10,813,000. NRC notes, however, that these estimated cost savings will not necessarily result in lower charges to licensees.

Based on OMB guidance, lifetime costs are estimated using a seven percent discount rate, which approximates the marginal pre-tax real rate of return on an average investment in the private sector in recent years.

Using both a seven percent discount rate and a 20-year time-horizon (i.e., base year plus 20), NRC estimates the lifetime cost savings of revising 10 CFR Part 35 to be approximately $125 million in year 2000 dollars.

7. DECISION RATIONALE

7.1 Decision rationale for revisions to 10 CFR Part 35

1. Alternative 2 is less expensive than Alternative 1 (status quo).

7.2 Decision rationale for PRM–20–24

1. All of the alternatives are acceptable according to generally accepted radiation protection principles, such as those expressed by NRC, NCRP, IAEA and ICRP (see Section 4.3, Evaluation of the Alternatives with Respect to Accepted Radiation Protection Principles).

2. Alternative 1 (status quo) is the least expensive to the public compared to Alternative 2, but Alternative 1 also conveys the least physical and emotional benefit to the patient. If the qualitative benefits of increased visitor-patient access is overlooked, a benefit which has not been expressed in dollar terms, the additional cost of Alternative 2 relative to Alternative 1 is about $334,800 per year. The preponderance of this additional cost is associated with badging visitors and providing ALARA instruction.

3. Alternative 1 and Alternative 3 have essentially the same relative licensee costs. The major difference is the qualitative benefits that the patient and visitor receive under Alternative 3.

4. Alternative 3 relative to Alternative 2 also has a net cost differential of $251,050 per year, mostly due to less prescriptive nature of the alternative in that there is no requirement to provide dosimetry and basic radiation safety instruction for each visitor and there are reduced recordkeeping requirements. Also, both Alter-

native 2 and Alternative 3 bestow similar qualitative benefits to the patient and visitors because of the increased visitor access. Thus, Alternative 3 is more cost effective in comparison with Alternative 2.

8. IMPLEMENTATION

No impediments to implementation of any of the alternatives have been identified.

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RESPONSES BY RICHARD MESERVE TO ADDITIONAL QUESTIONS FROM SENATOR VOINOVICH

Question 1. The NRC did a great job processing the first two license renewal applications at Calvert Cliffs and Oconee within the planned time. However, you are receiving multiple applications and I expect you will be receiving even more. What steps are you taking to ensure that you can process them all without creating a bottleneck at the NRC? Are there any lessons you learned in the first two applications which will allow the NRC and the applicants not to reinvent the wheel for each review?

Response. The NRC recognizes the potential resource impacts of the unexpected receipt of a large number of renewal applications and has encouraged licensees to inform the NRC of their plans for license renewal.

As part of the NRC's efforts to improve its processes, detailed procedures have been developed to conduct and monitor licensing actions, including the renewal reviews. The Commission is taking particular care to ensure that the review of license renewal applications is focused on those matters relevant to maintaining plant safety for the extended period of operation.

A standard format has been established for license renewal applications based on experience with the first reviews. The format is incorporated into the regulatory guide and standard review plan for license renewal.

In the summer of 2001, the NRC will issue a revised regulatory guide and standard review plan for implementing the license renewal rule, 10 CFR Part 54, that incorporate experience gained from the review of the first renewal applications. The standard review plan will also incorporate by reference the Generic Aging Lessons Learned (GALL) Report. The report documents generically the basis for determining when existing programs are adequate and when existing programs should be augmented for license renewal.

Use of the GALL Report will help focus the information provided by an applicant in a renewal application and the staff's review to areas where augmentation of an existing program is required or a plant-specific program is proposed. A reduction in the level of effort needed to prepare and review a renewal application is expected as a result of licensee and staff reliance on the GALL report.

The effort expended and outcomes of the license renewal reviews are being carefully monitored to ensure that the process is effective and efficient. The NRC's License Renewal Steering Committee is overseeing the license renewal process to ensure that the license renewal reviews are timely and efficient.

Lessons learned in the effectiveness and efficiency of the license renewal reviews continue to be collected so they can be included in future revisions to the procedures for conducting the license renewal reviews, changes to the NRC's implementation guidance documents, and changes to industry guidance.

Question 2a. In a letter from Dr. Edward Silberstein from the Department of Nuclear Medicine at University Hospital in Cincinnati, Dr. Silberstein states:

> Currently amendments to 10 CFR Part 35 are before OMB for Review. In my opinion the proposed NRC regulations add to the cost of health care without improving patient safety. These new NRC regulations will unnecessarily increase my work burden and thus increase the costs to patients who benefit from the more than 13 million procedures (such as cardiac stress tests, lung scans for pulmonary embolism and bone scans for cancer) we perform annually using radioactive materials regulated by the NRC.

Could you comment on this?

Response. The Commission opted to restructure 10 CFR Part 35 into a more risk-informed, more performance-based regulation by focusing on those medical procedures that pose the highest risk from a radiation safety standpoint. Risk information was used to determine what requirements are necessary to ensure radiation safety during the medical use of byproduct material. This resulted in reduction of regulatory burden by eliminating or decreasing the prescriptiveness of various requirements that apply to the lower-risk area of diagnostic medical procedures. The procedures mentioned in this question (cardiac stress tests, lung scans, and bone scans) fall into the lower-risk category of diagnostic medical procedures where the regulatory burden was reduced by making the rule more risk-informed and more performance based. The Final Regulatory Analysis for the 10 CFR Part 35 rulemaking contains a detailed section-by-section analysis of the costs of the new rule as compared to the current rule. Summing the new costs and cost savings, the Final Regulatory Analysis estimates that the revisions to 10 CFR Part 35 will result in a total annual cost savings of $8,836,000 to medical licensees in NRC and Agree-

ment States. The Final Regulatory Analysis was provided to OMB along with the Part 35 rulemaking for OMB review.

Question 2b. In a letter from Dr. Edward Silberstein from the Department of Nuclear Medicine at University Hospital in Cincinnati, Dr. Silberstein states:

> Currently amendments to 10 CFR Part 35 are before OMB for Review. In my opinion the proposed NRC regulations add to the cost of health care without improving patient safety. These new NRC regulations will unnecessarily increase my work burden and thus increase the costs to patients who benefit from the more than 13 million procedures (such as cardiac stress tests, lung scans for pulmonary embolism and bone scans for cancer) we perform annually using radioactive materials regulated by the NRC.

I also understand that the NRC ignored the advice of the National Academy of Science, Institute of Medicine. Could you also comment on this?

Response. The National Academy of Sciences, Institute of Medicine (NAS-IOM), study was conducted to provide the NRC with an independent evaluation of whether the rules, policies, and procedures of the current regulatory framework for medical uses of byproduct material fulfilled the NRC's statutory responsibilities for public health and safety.

In its report, the NAS noted that quantifying levels of risk in radiation medicine is problematic, and stated that no comprehensive raw data are available to make exact comparisons. The report did include risk assessment information addressing the information on comparative risks of ionizing radiation in medicine. During the rulemaking process, the Commission comprehensively evaluated and considered all aspects of the NAS report. Based upon our evaluation, and coupled with comments received from State and Federal agencies, the Commission determined that it should remain the lead Federal agency involved in the regulation of ionizing radiation in medicine.

Question 3. What can Congress and the NRC do to encourage more generation from our existing nuclear fleet?

Response. At the outset, it is important to recognize that pursuant to the Energy Reorganization Act of 1974, the NRC's mission is to ensure the adequate protection of public health and safety, the common defense and security, and the environment in the application of nuclear technology for civilian use. The Commission does not have a promotional role—rather, the agency seeks to ensure the safe application of nuclear technology.

The Commission recognizes, however, that its regulatory system should not establish inappropriate impediments to the application of nuclear technology. As a result, the Commission has implemented or is in the process of implementing several significant initiatives to maintain or enhance safety while simultaneously improving the efficiency and effectiveness of our regulatory system to support more generation from existing nuclear facilities. Some of the notable initiatives are the NRC's review of power uprate, and license renewal applications, reducing unnecessary regulatory burden through risk-informed regulations and the regulatory oversight process. The Commission believes that its initiatives should result in achieving economic efficiency while ensuring safe and reliable operation of nuclear facilities.

The Commission submitted proposed legislation to Congress that would help eliminate artificial restrictions and reduce the uncertainty in the licensing process. Although these changes may have little or no immediate impact on electrical supply, they would help establish the context for consideration of nuclear power by the private sector without any compromise of public health and safety or protection of the environment. For example:

- Legislation will be needed to extend the Price Anderson Act. The Act, which expires on August 1, 2002, establishes a framework that provides assurance that adequate funds are available in the event of a nuclear accident and sets out the process for consideration of nuclear claims. Without the framework provided by the Act, private-sector participation in nuclear power would be discouraged by the risk of large liabilities.
- Commission antitrust reviews could also be eliminated. As a result of the growth of Federal antitrust law since the passage of the AEA, the Commission's antitrust reviews are redundant of the reviews of other agencies. The requirement for Commission review of such matters, which are distant from the Commission's central expertise, should be eliminated.
- Elimination of the ban on foreign ownership of U.S. nuclear plants would be an enhancement since many of the entities that are involved in electrical generation have foreign participants, thereby making the ban on foreign ownership increasingly anachronistic. The Commission has authority to deny a license that would be inim-

ical to the common defense and security, and thus an outright ban on all foreign ownership is unnecessary.

STATEMENT OF JOE F. COLVIN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NUCLEAR ENERGY INSTITUTE

Chairman Voinovich, Ranking Member Lieberman and distinguished members of the subcommittee, I am Joe Colvin, president and chief executive officer of the Nuclear Energy Institute, the Washington, DC, policy organization for the nuclear industry. I am pleased to testify regarding the performance of the commercial nuclear industry and the industry's safety regulator, the Nuclear Regulatory Commission.

The Nuclear Energy Institute (NEI) coordinates industry policy on various issues affecting the nuclear energy industry, including Federal regulations that help ensure the safety of the 103 commercial nuclear power plants operating in 31 States. NEI represents 275 companies, including every U.S. utility licensed to operate a commercial nuclear reactor, their suppliers, fuel fabrication facilities, architectural and engineering firms, labor unions and law firms, radiopharmaceutical companies, research laboratories, universities and international nuclear organizations.

First, I will provide an overview of the industry's recent performance. Then I will discuss several topics related to the regulatory oversight, including:

- the new reactor oversight process
- the need for continued regulatory change
- Federal radiation protection policy
- renewal of the Price-Anderson Act
- revisions needed in the Atomic Energy Act

I. NUCLEAR POWER PLANTS OPERATING AT RECORD LEVELS OF SAFETY AND EFFICIENCY

The industry's performance continues to be outstanding by any measure. After a decade of steady improvement, U.S. nuclear power plants achieved record safety and reliability levels in 2000. The industry set another production record, generating 754 billion kilowatt-hours—3.5 percent more than in 1999. The average capacity factor for reactors nationwide in 2000 was nearly 90 percent. A 1,000-megawatt reactor, operating at 90 percent capacity factor, could provide electricity for 584,000 people, if all their uses of electricity are considered (including residential, commercial, industrial and public sector). That number is roughly equivalent to the population of Boston, Seattle or Austin, Tex.

The commercial nuclear industry in the United States is a dynamic, growing sector that has played a key role in the economic growth of our Nation. The increased electricity generation from nuclear power plants in the 1990's was equivalent to adding 23 new 1,000-megawatt plants to our nation's electrical grid. This output satisfied 22 percent of the increase in U.S. electricity demand that occurred in that decade.

The U.S. Energy Information Administration—in a March report titled *Nuclear Generation: Another Year, Another Record* said "the increase in nuclear generation over the past 2 years would have been enough to meet the power needs of all residential consumers in California in 1999."

The growth in nuclear electricity production is primarily the result of two factors. The first is that nuclear plants are operating more efficiently. Refueling times have decreased and once common unscheduled shutdowns are rare. The second factor is that many nuclear plants have undergone equipment uprates, allowing them to produce more electricity than was initially planned.

There has not been any nuclear plant event that has jeopardized public health and safety due to the release of radiation in the United States. Safety at our nation's nuclear power plants remains at record high levels. In 2000, the median number of unplanned reactor shutdowns industrywide was zero for the third straight year, and 59 percent of U.S. reactors had no automatic shutdowns. In addition, the number of significant events at U.S. nuclear power plants declined to an average of 0.03 in 2000, compared to 0.44 in 1990. Significant events include a degradation of important safety equipment, a reactor shutdown with complications, or operation of the plant outside technical specifications.

Nuclear power plants are the low-cost leaders in competitive electricity markets. Production costs at nuclear power plants (1.83 cents per kilowatt-hour) in 1999 were the lowest for any expandable large electricity source, including coal (2.07 cents) and natural gas (3.52 cents).

The recent energy shortfalls in some regions of the country have resulted in a growing recognition that new nuclear power plants will soon be needed to meet increased demand and to help protect our nation's air quality. In the January 11 edi-

tion of USA Today, Massachusetts Institute of Technology economics professor Lester Thurow said:

> Americans are not going to go without electricity, and they aren't going to quit driving . . . In the case of electricity, we already have a technical solution at hand. It is called nuclear power.

The industry has been evaluating the business conditions necessary to build new nuclear plants in the near future. An industry task force is producing a business plan to chart a course for potential reactor orders within the next 3 to 5 years.

Today's energy shortfalls are increasing public support for building new nuclear power plants, according to public opinion surveys conducted in January and March. The national survey of 1,000 adults found those in favor of "definitely building more nuclear energy plants in the future" increased from 42 percent in October 1999 to 66 percent in March. The increase was largest in the West, where those in favor increased from 33 percent in October 1999 to 62 percent. (Bisconti Research Inc., margin of error ±3 percentage points.)

Federal and State legislators and local government officials, as well as the national news media, also are reexamining nuclear energy, and supporting a vital role for the rejuvenated industry.

II. NUCLEAR GENERATION ESSENTIAL TO PROTECTING U.S. AIR QUALITY

For decades, nuclear energy has played a vital—though largely unrecognized—role in protecting our air quality. Between 1973 and 1999, nuclear plants avoided the emission of 32 million tons of nitrogen oxide, 62 million tons of sulfur dioxide and 2.6 billion tons of carbon.

A few examples will help put these numbers in perspective. Operating a 1,000-megawatt power plant for 1 hour produces one million kilowatt-hours of electricity.

- If the facility is a coal-fired plant, it also produces 265 tons of carbon.
- If it is an oil-fired plant, it produces 220 tons of carbon.
- If it is a gas-fired plant, it produces 150 tons of carbon.
- But if it is a nuclear plant, it produces no carbon whatsoever.

Electric generating facilities have faced significant emission reduction requirements, especially because large, stationary sources of emissions are easier to regulate than small or mobile sources. But electric generating facilities that prevent air pollution to begin with—such as nuclear power plants—also have played a major role. An example from the transportation sector will help illustrate the contribution of avoided emissions due to using nuclear energy in place of fossil-fired generation. If the United States were to replace all its nuclear plants with pollution-emitting generation, our nation would have to take 135 million passenger cars off the road to keep carbon emissions from increasing. Fortunately, our nation does not have to make such a choice.

Consider the importance of nuclear energy in three Eastern States:

- In New Jersey, nuclear power plants accounted for 51 percent of total electricity generation in 1999. They also avoided substantial emissions: 80,000 tons of nitrogen oxide, 160,000 tons of sulfur dioxide and nearly 7 million tons of carbon.
- Nuclear energy generated 47 percent of the electricity in Connecticut—avoiding the emission of 30,000 tons of nitrogen oxide, 70,000 tons of sulfur dioxide and nearly 3 million tons of carbon.
- Nuclear energy generated 26 percent of the electricity in New York, avoiding the emission of 110,000 tons of nitrogen oxide, 200,000 tons of sulfur dioxide and 8.5 million tons of carbon.

For all three States, nitrogen oxide emissions are capped under the Environmental Protection Agency's ozone transport regulations. If Connecticut replaced its nuclear-generated electricity with power from emitting generation, the State's other generating sources would be under even more pressure to reduce emissions.

New York, New Jersey and 19 other States face the same issue to varying degrees. These States simply cannot meet the broad spectrum of clean air requirements unless they use nuclear energy for a substantial proportion of their electricity generation.

Nuclear energy is the only expandable large-scale source of electricity that is emission-free. Reports last year from the Energy Department's Energy Information Administration made a direct connection between increased production from nuclear plants and the fact that greenhouse gases and other emissions increased less than they otherwise would have. Similarly, the Nuclear Energy Agency of the Organization for Economic Co-operation and Development considers nuclear energy to be "consistent with the objectives of sustainable development."

The nuclear energy industry is a leader in protecting the environment—managing all its waste and byproducts, with no uncontrolled discharges of this material. Used

fuel is stored onsite, either in steel-lined pools or in specially designed steel-and-concrete containers. Byproducts that have low levels of radioactivity are packaged and sent to licensed disposal facilities designed to handle such waste.

In addition to helping to preserve our nation's air quality, the nuclear energy industry is a leader in protecting wildlife habitat, including the endangered American crocodile, manatee, eagles, osprey and other animals. Plant owners continually monitor and work to mitigate the impact of power plant operations on wildlife. For example, water intake structures have rolling screens to minimize the numbers of fish that are drawn into the plant cooling water system. On-site hatcheries replace the few fish that are drawn in. The waterways and grounds around nuclear plants are sanctuaries for many species of endangered wildlife.

In short, nuclear energy offers high levels of safety, reliability, price stability and careful stewardship of the environment. All of this is included in the cost of electricity from nuclear energy—and even so, these plants are competitive with other sources of electricity.

III. NRC REACTOR OVERSIGHT PROCESS MORE EFFICIENT, MORE TRANSPARENT TO THE PUBLIC

Outstanding nuclear power plant safety and performance helped set the stage for important changes in the regulatory arena. Last April, the NRC began implementing a new reactor oversight process that builds on decades of safe nuclear plant operating experience, both within the agency and the industry. The agency engaged many stakeholders, including the Union of Concerned Scientists and Public Citizen, in developing the new approach. The industry believes that the new reactor oversight process is more effective and efficient than the previous oversight process because of its sharper focus on those areas of the plant most important to safety. It also is a major step forward in making a complex, technical process more transparent to the public.

The baseline program concentrates on plant activities and systems with the greatest potential impact on public safety and overall risk. This safety-focused approach is linked to the NRC's three oversight areas—inspection, assessment and enforcement.

The level of agency resources to be applied in oversight depends on how a plant performs as measured by the performance indicators and inspection findings. Performance in each indicator is measured quarterly and falls into one of four color-coded bands:

- *Green:* Performance is within an expected range in which safety cornerstone objectives are being met.
- *White:* Performance is outside an expected range of nominal utility performance, but related cornerstone objectives are still being met.
- *Yellow:* Related cornerstone objectives are being met, but with a minimal reduction in safety margin.
- *Red:* There has been a significant reduction in safety margin in the area measured by that performance indicator.

For a program involving change of this magnitude, the initial implementation has gone well. The process has succeeded in identifying performance differences among plants from the critically important perspective of safety. The fourth-quarter 2000 performance indicator data and inspection findings showed that the vast majority of nuclear power plants are performing at very high safety levels. Based on the performance indicator data and inspection findings for the first 9 months[1] of the program, the NRC concluded that:

- 73 reactors had all green indicators—the best of four NRC performance levels—and need the baseline level of inspection;
- 22 reactors received supplementary inspections because they received a single white indicator or inspection finding; performance in the area measured by that indicator is outside the expected range, but safety objectives are being met; and
- 6 reactors are receiving more in-depth inspections because of possible weaknesses in more than one performance area. Nonetheless, these plants are being operated safely.

The results of the performance assessments are consistent with nuclear plant performance of the past several years. The new process makes it much easier for plant operators and the public to see how nuclear plants are performing and to identify any areas in need of increased attention. On the NRC's Web site, the public can find the underlying technical details in a given performance area. Greater public

[1] Two reactors at the D.C. Cook nuclear power station are excluded because they have not accumulated enough data under the new process to be representative of their performance.

awareness of how nuclear power plants are regulated was one of the major goals of the new oversight process, and the NRC should be commended for its achievement.

The NRC commissioners and staff have shown a strong commitment to modernizing the agency's regulatory approach. The industry believes that the NRC's new approach will continue to improve safety performance by focusing industry and NRC resources on those issues that have the greatest safety importance. Given this success, the industry encourages the NRC to develop a safety-focused oversight process for non-reactor facilities based on similar principles.

IV. NEED FOR CONTINUED REGULATORY CHANGE

Changes to NRC Regulations

The new oversight process is an enormous improvement over the agency's former approach to evaluating nuclear plant safety. It is objective, safety-focused and much more transparent to industry and the public. But it is only a first step in needed regulatory reform.

Interestingly, the NRC did not have to change any regulations to implement its new reactor oversight process. However, regulatory reforms must be codified. The next step is to revise the regulations to incorporate risk insights and performance-based approaches consistent with those used in the reactor oversight process.

In creating the new reactor oversight process, the NRC recognized that not all of its regulations have equal importance—that some regulations add little or no safety benefit.

The NRC is revising its regulations to make them more safety-focused, but progress has been slow. A central component of this effort involves deciding how to treat equipment that previously was categorized as "safety-related," but which has been proven to have little or no safety significance.

The industry started designing and building nuclear power plants 40 years ago, without operating experience or the sophisticated analytical tools we have today. There was at that time some uncertainty associated with commercial nuclear power plants. Given the limited nuclear plant operating experience at that time, the industry and Federal regulators correctly made conservative decisions based on worst-case scenarios. A very large number of systems and equipment were assumed to have high safety significance.

Today, we combine more than 2,500 reactor-years of operating experience with sophisticated computer models for probabilistic safety assessments. The result is a much higher degree of certainty about how nuclear plant systems behave and interact under a wide range of conditions. Recent safety studies have demonstrated that fewer plant systems and equipment have high safety significance.

The NRC and the industry agree on which equipment has high safety significance and on how to treat it. We also agree on equipment that is non-safety-related.

But there is disagreement about how to deal with equipment and systems categorized since the early years of the industry as safety-related, but which have been proven to have low safety significance. The industry believes that commercial industrial standards, not more stringent nuclear safety standards, should be applied to such equipment. Commercial industrial standards are widely used in the nuclear industry, as well as other industries with similar or higher potential impact on public health and safety.

The cost savings for replacement parts at reactors—and for initial construction for new reactors—is substantial. For example, an industrial-grade 10-horse-power electric motor could be purchased for $350. The same motor, purchased as a safety-related item, would cost 57 times that amount: $20,000. The two pumps perform the same function; but the cost difference is huge.

Similarly, an industrial-grade electrical circuit card could be purchased for $1,160. The same circuit card, under nuclear standards, would cost $5,700—five times as much as the industrial-grade item. Either component could perform the function for which it is intended.

The main difference in cost is the extent of the process used to verify the component's performance capability. Commercial industrial standards are entirely satisfactory for many applications with low safety-significance in nuclear power plants. In fact, they already are widely used in these facilities. Their use could be expanded substantially, and it simply makes sense to do so.

New Nuclear Power Plant Licensing

New nuclear power plants will be needed to meet both electricity demand and our nation's air quality goals. When the NRC began efforts to modernize its regulations, the industry believed that the new risk-informed regulations would provide the

framework for licensing new nuclear power plants. However, a separate rulemaking will be needed for two reasons:

- It is the most straightforward approach. Changes to existing regulations must take into account the outdated assumptions embedded in the regulations and the plants designed and built to meet them.
- The NRC's work on modernizing current regulations is moving too slowly to be completed in time to license new nuclear power plants in a more safety-focused manner.

The scientific and technical skills needed to license new nuclear power plants differ from those needed for oversight of today's nuclear plants—which has been the NRC's principal activity for the past 15 years—or in license renewal. To review applications for new licenses, the agency will need geologists, hydrologists, and other scientists. Current NRC staff may not have the appropriate expertise for this new function. To prepare for new nuclear power plant construction and operating license applications, the NRC should examine its staffing and determine how to fill any gaps in its expertise. Similarly, the industry, university, Federal agencies and national laboratories must ensure that we have the expertise and qualified staff for the development and staffing of future nuclear technologies. The industry supports a multi-stakeholder effort to attract and retain top caliber nuclear talent and encourages Congress to continue funding university programs in nuclear technologies. Congress also should support the essential role of nuclear energy in the development of national energy policy as well as legislation introduced this year to support the development of expertise for the future.

NRC Budget and Staffing

As an independent agency, the NRC was not required to develop a 5-year, strategic plan—but to its credit, the agency took the initiative to do so. In the industry's view, the current plan is fundamentally sound. However, we believe that the plan can be improved further and used to more directly tie the NRC's strategic goals to its day-to-day operations. A robust 5-year plan—one that is used to identify goals and allocate resources—will enhance the agency's effectiveness.

The NRC is facing increased demands on its staff because of license renewal applications, the development of risk-informed regulations and the development of regulations to license new plants. Although these activities will require substantial resources, the industry believes the NRC's current budget and staffing levels can adequately support these initiatives if the agency allocates resources on a priority basis.

The NRC's capability to evaluate nuclear plant systems, structures and components on a safety-focused basis has demonstrated that the scope of safety-significant activities is substantially smaller than previously thought. These insights identify clear opportunities for the NRC to realign its current resources to face new challenges without expanding the size of its staff.

The new reactor oversight process demonstrates that nuclear power plants are performing safely. The few plants that warrant additional regulatory attention are clearly identified. The level of NRC resources dedicated to plant inspections should be adjusted to reflect the priorities identified by the new oversight process. In addition, the regional deployment of these resources may be no longer appropriate.

The nuclear energy industry is well established, and nuclear assets are being transferred during a transition to electric utility restructuring. This has resulted in nuclear plants being operated by a smaller number of experienced nuclear operating companies, which operate in multiple regions. We see regional differences in how inspections are conducted under the new oversight program. These differences send mixed signals to the management of these companies and indicate that the regional structure may perpetuate cultural resistance to the commission's efforts to modernize its regulatory process.

The successful implementation of the revised reactor oversight process and the natural consolidation of the nuclear industry provide an opportunity for the commission to re-allocate existing resources to meet the combined challenge of safety-focusing reactor regulations and preparing to license new reactor designs.

In short, the NRC should be asked to demonstrate that it is using its existing staff optimally on matters central to the agency's statutory mandate—protection of public health and safety—before asking for additional resources to support new activities.

General Accounting Office Report

The industry's record performance has coincided with several major regulatory initiatives: the transition to safety-focused regulation, implementation of the new reactor oversight process and successful license renewal proceedings.

A recent General Accounting Office (GAO) report—*Major Management Challenges and Performance Risks: Nuclear Regulatory Commission*—noted that the NRC faces challenges of changing its culture to fully support the safety-focused regulatory concepts reflected in the NRC's new reactor oversight process. However, GAO expressed concern about the NRC's ability to continue to ensure safe operation of nuclear facilities while it is pursuing major change initiatives.

Although that concern is not unreasonable, the record plainly shows that regulatory reform efforts have had no adverse impact on industry safety. In fact, the new oversight process has improved safety by more clearly identifying what is important to safety—and just as important, what is not.

V. FEDERAL RADIATION PROTECTION POLICY MUST BE BASED ON SOUND SCIENCE

As the industry works to increase energy production, it is committed to maintaining the highest priority on safety. Achieving this goal depends in large part on the Federal Government's setting a uniform radiation protection policy. The policy should be based on the best available science and should be applied equitably and consistently by every Federal agency across all programs. Duplicative and conflicting regulation by different agencies, using different criteria, must be eliminated.

In this area, Federal radiation protection policy falls short. In fact, a recent report from the General Accounting Office—*Radiation Standards: Scientific Basis Inconclusive, and the EPA and NRC Disagreement Continues*—concluded that U.S. radiation protection standards "lack a conclusively verified scientific basis," involve "differing exposure limits" due to policy disagreements between Federal agencies, and "raise questions of inefficient, conflicting dual regulation." A troubling conclusion of the GAO report is that the costs related to complying with such standards "will be immense, likely in the hundreds of billions of dollars" of private and public funds.

Two examples of this situation that directly affect consumers include Federal standards for the decommissioning of NRC-licensed facilities and for the proposed used nuclear fuel repository at Yucca Mountain, Nevada. In both cases, the EPA and the NRC have statutory authority to set radiation standards. The two agencies have taken fundamentally different regulatory approaches, and the standards they have set differ accordingly. The NRC has based its standards on sound, scientific principles, whereas the EPA has stated that its groundwater policy is based "on policy, not science."[2] This difference has complicated development of the Yucca Mountain repository, as well as facility decommissioning projects by NRC licensees.

This situation creates significant uncertainties in projecting costs and schedules. These uncertainties adversely affect a wide range of decisions, including:

- Federal budgeting and site suitability for Yucca Mountain;
- mergers and acquisitions within the electric industry;
- deregulation of the electricity industry;
- expansion of nuclear energy through license renewal for today's plants and the licensing and building of new plants.

Moreover, these negative impacts occur without any demonstrated positive benefit to public health and safety.

Federal radiation protection policy must provide a foundation to protect public health and safety, make the best use of public funding and resources, and help build public trust and confidence in Federal decisions. Today's conflicting radiation standards and duplicative regulation work against those principles.

This situation has persisted for years, without any substantial progress made toward resolution. For example, Senator John Glenn, as chairman of the Senate Committee on Governmental Affairs, asked the GAO to report on this issue in 1994. The GAO issued a report in September—*Nuclear Health and Safety: Consensus on Acceptable Radiation Risk to the Public is Lacking* (GAO/RCED–94–190). Senator Pete Domenici requested a follow-up report in 2000. That report—*Radiation Standards: Inconclusive, and EPA and NRC Disagreement Continues* (GAO–00–152) reflected a situation essentially unchanged. In 6 years, there had been virtually no progress in resolving the issue.

Congress should resolve the policy issues that the agencies have not resolved on their own. We encourage this committee to provide appropriate, continued oversight to ensure that consistent radiation policy is established through legislation.

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[2] This response can be found in written answers dated September 18, 2000, to questions submitted to the EPA by Rep. Joe Barton, chairman of the Subcommittee on Energy and Power of the Committee on Commerce.

VI. PRICE-ANDERSON ACT MUST BE RENEWED

The U.S. public has more than $9.5 billion of insurance protection if an accident were to occur at a commercial nuclear facility. This entire sum would be paid by the nuclear industry. The framework for this insurance coverage was established in 1957 by the Price-Anderson Act, which expires on August 1, 2002. It is a proven system that Congress should reauthorize. The act requires each nuclear facility to have that insurance coverage to satisfy its statutory obligations. Neither taxpayers nor the government pay a cent for this coverage.

Like all the costs of electricity from nuclear power plants, the costs of Price-Anderson are internalized. That means the nuclear industry bears the cost of insurance, unlike the corresponding costs of some major power alternatives.

Risks from dam failure and resultant flooding, for example, are borne directly by the public. The 1977 failure of the Teton Dam in Idaho caused $500 million in property damage. The only compensation for this event was about $200 million made available through low-cost government loans.

The Price-Anderson Act requires two levels of financial protection. The primary level provides liability insurance coverage of $200 million insurance that is purchased by the utilities.[3] If this amount is not sufficient to cover claims arising from an accident, a secondary level applies. For the second level, electric companies that own nuclear power plants must pay a retroactive premium equal to their proportionate share of the excess loss. That amount is $10 million per year, up to a maximum of $88.1 million per reactor. Currently, 106 nuclear reactors participate in the secondary financial protection program—103 operating reactors and three closed reactors that still handle used nuclear fuel.

Congress must renew the act this year to ensure that Price-Anderson coverage will be available to companies that are considering building new nuclear power plants. Renewal also is vital to Energy Department contractors, which are indemnified under the Price-Anderson Act. Nuclear power plants are grandfathered under the act; DOE contractors are not. The continued operation—and, where necessary, the cleanup—of Federal sites depends on timely renewal of the Price-Anderson Act's provisions. Both the Nuclear Regulatory Commission and the Energy Department have recommended that Congress renew the act. The industry generally supports the NRC positions on the issue, but differs from the agency in three important areas:

• Permanent renewal is preferable to a 10-year renewal. Like any law, Congress can reconsider this issue if circumstances change.

• The retrospective premium should remain at $10 million. The NRC recommends that Congress consider increasing it to $20 million per reactor from $10 million per reactor. The NRC recommendation was based, in part, on the assumption that up to 25 current plants would be retired without relicensing and that the total insurance coverage would decrease as a result. It now appears that the vast majority of nuclear plants will pursue license renewal.

• The level of primary insurance coverage should remain at $200 million. The NRC recommends that consideration be given to increasing the primary coverage of insurance to $300 million, but there is no justification for increasing this insurance coverage.

The industry appreciates this committee's efforts to begin consideration of this issue in the 106th Congress, with Senator Inhofe's introduction of S. 2292, the Price-Anderson Amendments Act of 2000.

VII. CHANGES NEEDED TO ATOMIC ENERGY ACT

The industry believes several changes are needed to the Atomic Energy Act to facilitate reform of the NRC and its regulatory processes to ensure the effective and efficient regulation of NRC licensees. Other changes are needed to remove unnecessary impediments that would inhibit the ability of nuclear power plant operators to make the transition from a cost-of-service market to a competitive market. The nuclear industry recommends the following changes:

• Congress should remove the requirement that the NRC conduct antitrust reviews. Other Federal agencies conduct such reviews—notably the Securities and Exchange Commission, the Federal Trade Commission and the Federal Energy Regulatory Commission. An additional review by the NRC is unnecessary.

• Congress should remove the restriction on foreign ownership of commercial nuclear facilities. NEI supports NRC-proposed changes to Sections 103d and 104d to

[3] Each utility/company purchases $200 million of primary insurance *per site* through American Nuclear Insurers. The total insurance available—$9.5 billion—includes the primary and secondary insurance available for an accident at one site.

clarify that no restrictions should be placed on the ownership of a production or utilization facility, except that no license should be issued if such issuance would be inimical to the common defense and security or public health and safety.

• Congress should clarify that the NRC has the discretion to determine the most appropriate form of hearing to hold in each circumstance and that the agency is not required to hold adjudicatory hearings for licensing proceedings unless it determines that such a proceeding is necessary.

• Congress should clarify that in the case of a combined construction and operating license for a nuclear power plant, the start of the operating license term is keyed to when operation begins, rather than when the license is initially issued.

• Congress should authorize the NRC to recover costs from other Federal agencies for services it provides to those agencies.

• Congress should clarify that Federal law preempts State insurance laws and constitutional provisions that would restrict insurers that satisfy NRC requirements from providing insurance to nuclear facilities.

• Congress should give the NRC the legislative authority to allow the seller of a nuclear power plant to retain a decommissioning fund even though the seller may no longer be an NRC licensee.

• The NRC has made considerable progress toward modernizing its regulatory efforts. NEI supports the elimination of Sections 203, 204, and 205 of the Atomic Energy Act. The commission should be given the discretion to organize and manage the NRC in the manner it deems most appropriate.

• Congress should give the NRC legislative authority over accelerator-produced radioactive materials. Currently, there is no Federal guidance for these materials.

• Congress should give the NRC legislative authority over technically enhanced naturally occurring radioactive material. Currently, Federal guidance is limited to naturally occurring radioactive material, which is not scientifically consistent when the material is concentrated.

Many of the above proposals were included in S. 1627 as passed by the Senate in the 106th Session of Congress. NEI thanks this subcommittee and the full Environment and Public Works Committee for its work on these issues.

NEI has reviewed the legislative proposals that the NRC forwarded to Congress in a letter dated February 28, 2001. The nuclear industry commends the NRC for those initiatives and urges this subcommittee to support such legislation.

SUMMARY OF KEY POINTS

• Initial implementation of the NRC's new reactor oversight process has gone smoothly. This process must continue, and the underlying principles must be expanded to the remainder of the NRC's regulatory process. I urge the committee to support safety-focused regulatory processes. In addition, the committee should examine how these changes, as well as the increased needs for possible new plant licensing, will impact NRC staffing levels.

• The next step in regulatory reform is to revise the regulations to incorporate risk insights and performance-based approaches consistent with those used in the reactor oversight process. This committee should continue its careful oversight of the NRC and request regular reports from the agency detailing the progress it is making on codifying the new regulatory process.

• The Federal Government must establish science-based, uniform standards for radiation protection, under the oversight of a single Federal agency. It is clear that legislation will be needed, and the industry asks this committee to ensure that this action is taken.

• The Price-Anderson Act must be renewed this year. The act provides the legal framework for nuclear facility insurance coverage, which for commercial facilities is funded by the industry. The Price-Anderson Act is a necessary element in assuring the public that the industry is prepared for contingencies.

• Many changes have taken place since the last major revision to the Atomic Energy Act, the fundamental legislation that established our nation's nuclear programs. Several revisions are needed to remove unnecessary impediments for nuclear power plants as they transition to a competitive marketplace. The industry urges the committee to support legislative action to amend the act.

CONCLUSION

Nuclear energy is the only large source of electricity that is both emission free and readily expandable. Its safety record, reliability, cost effectiveness and price stability make nuclear energy a vital fuel for the future. That is clear from the current U.S. energy situation, which is marked by thinning capacity margins and volatile prices for fossil fuels.

In the future, as electricity demand continues to rise, nuclear energy will be even more important to American consumers—and to our nation's economy as a whole. Our nation's nuclear power industry has proven over the past two decades that nuclear energy is a reliable, efficient, and safe source of electricity for our nation's economic growth. I urge the members of this committee to support the role of nuclear energy in the U.S. energy mix.

Thank you for giving me this opportunity to share the industry's perspective on oversight of nuclear facilities and several related matters.

RESPONSES BY JOE F. COLVIN TO ADDITIONAL QUESTIONS FROM SENATOR REID

Question 1. How many nuclear power plants have significant foreign ownership?

Response. Federal law, Section 103d of the Atomic Energy Act, currently precludes foreign corporations, or one if its subsidiaries, from owning a controlling interest in a commercial nuclear power plants in the United States or a NRC licensee that operates a plant. As such, there is no significant foreign ownership of U.S. nuclear power plants.

Of the 103 operating nuclear units in the United States, only three are owned, in part, by a foreign company. Those plants include Three Mile Island Unit 1, Clinton and Oyster Creek. All three plants were purchased in 1999 and 2000 by AmerGen Energy Co., a 50/50 joint venture between PECO Energy (which merged last year with Unicom to form Exelon), and British Energy, of Edinburgh, Scotland.

NEI and the NRC have urged Congress to eliminate the blanket restriction in Section 103d. The NRC would still retain the authority to ensure that any licensing action it takes is consistent with pubic health and safety requirements and is not inimical to national defense and security. Other Federal laws that also apply to American businesses in general, including commercial nuclear power plants, prohibit foreign ownership of American corporations if such ownership is inimical to our national security interests.

A restriction on foreign ownership of commercial nuclear power plants is an unnecessary barrier to an important source of capital. Competing producers of electricity in the United States, such as wind, solar, biomass, coal and gas plants, are not burdened with a blanket restriction such as Section 103d. Foreign ownership of a commercial nuclear power plant does not *per se* impose a threat to our national security interests.

Question 2. How many of the principal nuclear power engineering, maintenance and equipment supply companies have significant foreign ownership?

Response. Federal law, Section 103d of the Atomic Energy Act, that restricts the foreign ownership of commercial nuclear power plants in the United States, does not similarly restrict the foreign ownership of other nuclear power-related businesses. The nuclear energy industry is a worldwide enterprise. Non-U.S. companies have a growing presence in the U.S. market, which reflects their conviction that the United States represents an attractive business opportunity. U.S. companies have significant financial interests in overseas markets.

Subsidiaries of British and French companies have the largest presence in the United States. BNPLs Inc., a wholly-owned subsidiary of British Nuclear Fuels, Ltd., has acquired the nuclear design/engineering assets of Westinghouse and ABB-Combustion Engineering. France's Framatome owns the nuclear business formerly owned by Babcock & Wilcox. In addition, France's Cogema and Urenco, the Anglo-German-Dutch company, have a significant presence in the U.S. nuclear fuel market.

These acquisitions of domestic nuclear assets by foreign corporations were fully reviewed by the Committee on Foreign Investment in the United States, an interagency committee chaired by the Department of the Treasury that was created pursuant to the 1988 Exon-Florio amendment to the Defense Production Act of 1950. Under that law, the President of the United States can prohibit the foreign acquisition of any domestic corporation if it found that such action would pose a threat to our national security. Additional information regarding the CFIUS can be found at *www.treas.gov/oii*.

Similarly, U.S. companies are active overseas. General Electric is building advanced light water reactors in Japan and Taiwan. ABB-Combustion Engineering is active in South Korea. USEC, Inc., the U.S. uranium enrichment company, is the world's largest supplier of uranium enrichment services, and has a 30–40 percent share of the non-U.S. market for enrichment services.

Question 3. The Administration has discussed reducing our dependence on foreign energy supplies. How do we accomplish that if our nuclear power industry is gaining

increasing foreign investment in both the generation, and maintenance and supply aspects of the industry?

Response. As noted above, the nuclear energy business—like petroleum, automobile manufacturing, information technology, banking and virtually every other commercial enterprise of note—is an international endeavor. U.S. energy companies have significant investments outside the United States. Foreign companies—largely from Britain and France, our longtime allies—have significant investments in the U.S. electric power business generally, and the nuclear energy sector specifically through U.S. chartered affiliates. Operations and production in all countries with nuclear electricity have benefited from the resultant sharing of best practices and capabilities to improve safety and efficiency around the world.

Domestic concerns with energy security and foreign energy dependence, either currently or historically, have not occurred due to foreign ownership of energy facilities by companies from trading-partner countries. Rather, energy security concerns arise when nations experiencing political instability are the source of necessary fuels that cannot be domestically supplied or sufficiently stockpiled so as to manage risks and costs from fluctuating supplies and prices. The only fuel for which this issue arises is oil.

The nuclear industry was developed to mitigate impacts to the environment in electricity production while acting as a risk management tool or hedging mechanism against such foreign oil supply and price problems. Nuclear fuel is safely stockpiled; the primary source countries for mined uranium are stable American allies and trading partners, and small fuel volumes can provide high volume, long-term electricity supply, making nuclear electricity a key underpinning of U.S. energy security.

U.S. energy security and U.S. vulnerability to foreign manipulation would be seriously compromised in the absence of nuclear energy. Its success in meeting energy security goals is borne out by the numbers—in 1973, at the time of the first oil embargo, oil provided approximately 20 percent of U.S. electricity supply; nuclear energy, only about 4 percent. By contrast, nuclear energy today represents approximately 20 percent of U.S. electricity supply; oil, only about 3 percent. Nuclear energy has thus displaced large amounts of oil (and other fossil fuels) that would otherwise have been required for electricity generation.

Nuclear fuel is also produced from source material redirected away from weapons use into peaceful energy production. This reuse reduces the risk of proliferation at the same time it produces electricity without harmful air pollutants or greenhouse gases—essentially turning "megatons" of destructive weaponry to "negatons" (no tons of potentially harmful emissions). The international cooperation and interaction reflected in these programs has been a hallmark of the nuclear industry since President Eisenhower first set the course for peaceful uses of this technology. And, by displacing the use of fossil fuels to preserve limited supplies, uranium fueled electricity also contributes to sustainable development. Fortunately, there is no indication that foreign ownership of nuclear international nuclear companies would do anything to change or impair the continued successful delivery of these energy, security, and environmental services.

Question 4. Significant research has gone into developing reactors with improved safety performance. How much research has the industry put into developing plants that have improved performance with regard to waste?

Response. Nuclear power's recognized improvement in waste elimination and management over existing electricity production methods was a primary reason for commercial nuclear electricity development as early as the 1950's and 60's. Since its inception, commercial nuclear electricity production has lead all industry in preventing, minimizing, and managing waste byproduct creation and introduction into the environment. Toxic air and water pollutants, the common waste materials generally created by electricity production, are avoided almost entirely in fission electricity. Heat waste is minimized and treated before release into water bodies or air. Fuel storage, either before or after use, does not require large areas for storage, or create leachate or other potentially harmful discharges. Because fission requires no end-of-the-pipe remediation for its air emissions, no secondary waste such as scrubber sludge is created, requiring disposal.

Approximately 40,000 tons of used nuclear fuel remains available as a secondary raw material for reuse and recycling to support future sustainable development, should it be needed as originally anticipated by the Federal government. Hazardous radioactive constituents naturally attenuate (degrade) without causing adverse environmental impacts, as fuel is safely stored in on-site facilities and ultimately, in a geologic depository. Building on this past success in used fuel and waste management, the U.S. nuclear industry continues to achieve significant progress in mini-

mizing volumes of used fuel created, as well as low-level nuclear waste that is treated and disposed at time of use.

Used Nuclear Fuel.—The industry has consistently supported research efforts to develop advanced nuclear plant designs that combine improved safety performance as well as improvements in high- and low-level nuclear waste management. In 1999, the Department of Energy (DOE) created the Nuclear Energy Research Initiative (NERI), a research and development program that seeks to remove barriers to the future use of nuclear energy. In addition to providing grants for development of advanced nuclear plants that are safer, more economic and more efficient, one of NERI's goals is to develop technology that will improve management of used nuclear fuel.

The industry's most significant success in minimizing volumes of used fuel produced has nothing to do with research programs, however. The most notable success is operational. During the 1990s, U.S. nuclear generating capacity actually declined by approximately 1,000 megawatts, yet production increased by 177 billion kilowatt-hours. This increase is approximately equal to the output from 22 new 1,000-megawatt power plants operating at a 90-percent capacity factor, and satisfied over 20 percent of the increase in U.S. electricity demand during the 1990s. This increase in productivity was achieved by operating more efficiently and reliably, obtaining more electricity from the same volume of fuel, without increasing the volume of used fuel produced. The volume of used fuel produced remained virtually constant through the 1990s (at approximately 3,000 metric tons per year) but the amount of electricity derived from the fuel increased by 23 percent.

Low-Level Waste.—Similarly, the volumes of low-level waste (LLW) produced by the commercial nuclear energy industry have declined dramatically. The LLW volumes produced by boiling water reactors have declined by 92 percent since 1980; the volumes produced by pressurized water reactors have declined by 96 percent during the same period.

Question 5. As you know, the construction of new nuclear plants will likely compete with natural gas turbine plants. How high does the cost of natural gas have to go to make building a nuclear power plant substantially more attractive to overcome the public mistrust of the industry and the extremely high capital and operating costs of nuclear power plants?

Response. Unfortunately, all forms of large capital projects are experiencing the effects of "nimbyism," which in turn can cause troubling effects for energy supply in the future. The challenge to all energy producers (including gas plants, which are failing to gain community approval around the country) is to site plants using our diverse menu of fuels so as to maximize the benefits to the communities, the economy, and the environment.

In order to make electricity in an environmentally preferable manner, all plants are being built to meet stringent environmental standards, especially with regard to air pollution and greenhouse gases. Fortunately, the cost of a nuclear plant includes the capital investment needed to eliminate potentially harmful air emissions-something no other baseload form of generation can do except for hydroelectric. Without a significant percentage of the electricity supply remaining emission-free (today its over 30 percent), it will be difficult, if not impossible, to build the new plants needed and remain within Clean Air Act standards.

Not only do nuclear plants have affordable capital and operating costs, investment in nuclear includes the avoided costs of many potential health and environmental impacts. In a recent letter to the Administrator of the U.S. EPA, Senators Jeffords and Lieberman both indicated that "the health and environmental benefits associated with emission reductions" were not adequately reflected in government analyses of the costs and benefits of controlling air pollutants. Omitting these benefits from calculations of the costs of nuclear plants creates the same cost distortions that the Chairman and Subcommittee Chairman point to, especially since nuclear plants use the best emission control technology available avoid making them in the first place.

The U.S. nuclear energy industry estimates that new nuclear power plants could be built in the United States for between $1,000 and $1,200 per kilowatt of capacity. The industry has a high level of confidence in these cost estimates for several reasons:

1. The cost estimates are for advanced light water reactor designs in which the industry and the Federal Government invested several hundred million dollars during the 1990s.
2. Thanks to this investment, these designs are essentially fully engineered.
3. Because so much of the engineering and design work is complete, it is possible to develop relatively precise cost estimates.

At this capital cost of $1,000–151,200 per kilowatt of capacity, new nuclear power units are fully competitive with the other alternatives for baseload electricity production, before the emission control benefits are accounted for.

The alternatives to new nuclear plants include:

1. *Conventional coal-fired power plants* with a full suite of environmental controls. Largely because of the significant increase in the cost of natural gas, which has increased the cost of electricity from gas-fired power plants, a growing number of new coal-fired projects are being proposed. These conventional coal-fired plants typically have capital costs in the range of $1,000–1,100 per kilowatt of capacity.

2. *The so-called "clean coal" technologies,* which have capital costs in the range of $1,200–1,500 per kilowatt of capacity. For example, Reliant Energy is building a 520-megawatt plant in Pennsylvania using a clean coal technology called atmospheric fluidized bed combustion. This project has a total capital cost of $800 million, for an overnight capital cost of approximately $1,500 per kilowatt of capacity. Over time, as more of these atmospheric fluidized bed plants are built, the technology developers expect to be able to reduce the capital cost. Their current target $1,000–1,200 per kilowatt.

Other "clean coal" technologies have higher capital costs than atmospheric fluidized bed combustion. An integrated gasification combined cycle (IGCC) plant currently has a capital cost of approximately $1,800 per kilowatt for the first plants built, according to estimates from the technology developers and data from the Department of Energy's clean coal technology program. The technology developers hope to reduce this capital cost to $1,200–1,500 as the technology matures and more of these plants are built. However, to attain any future emission limits (such as a "net" emission requirement for greenhouse gases, additional costs would be incurred that are already built into the price of a nuclear plant).

3. *New combined-cycle gas-fired power plants*, which have capital costs in the range of $600–700 per kilowatt of capacity. The total cost of these plants generally changes when the full suite of environmental controls required for impending emission limits is added. In many cases, control technologies like selective catalytic reduction (SCR) are difficult to obtain due to limited production, and can add cost or lower efficiencies when in operation. Often, capital costs must include additional pipeline and transmission feeders.

Unlike the nuclear and coal-fired technologies, gas-fired power plants are extremely sensitive to fuel prices. Economic analysis shows that a new nuclear unit at $1,000 per kilowatt of capacity is competitive with a new gas-fired combined cycle plant at a capital cost of $600 per kilowatt of capacity fueled with gas at $4–5 per million Btu. (Although wellhead gas prices in the spot market have slumped below $4 per million Btu in recent weeks, the cost of gas delivered to electricity generators remains well above $5 per million Btu in all major consuming regions of the United States except California. In California, delivered prices for natural gas are considerably higher, in the $10–15 per million Btu range.)

Public Attitudes to Nuclear Energy.—There is also increasing public support for continued operation of existing nuclear plants as well as for construction of new nuclear plants as concern about electricity shortages and prices spread across the nation. In recent polls of public opinion, 66 percent of adults in all regions of the country support building more nuclear power plants, compared to 42 percent in October 1999. The March 2001 survey also found increased support for renewing the licenses of nuclear plants. Eighty-seven percent agreed licenses should be renewed, up from 79 percent in October 1999.

Operating Costs.—Nuclear power plants are among the lowest-cost, economical sources of electricity in the nation. As a result of improved productivity and reliability over the past 10 years, U.S. nuclear plants are fully competitive in the deregulated, competitive electricity markets now evolving across the United States. On average, a nuclear power plant produces electricity at a total cost of approximately 2.0 cents per kilowatt-hour. This is comparable with large coal-fired power plants, and much less costly than electricity produced by power plants fueled by natural gas.

Question 6. Paul Joskow, an MIT economist, recently said referring to the price per unit capacity: "None of these deals even comes close to covering the book costs. You couldn't justify paying $2,000 or $3,000 per kilowatt for those plants." He added that investors would have to expect a huge competitive benefit from nuclear plants to risk putting money in a new one "because of the significant possibility of coming up with a dry hole." Do you agree with this assessment?

Response. We view the current situation for existing plant transactions and new construction differently from Mr. Joskow, and will separately address these two components in the question.

The first involves existing nuclear plants. The reference to "book costs" of "$2,000 to $3,000 per kilowatt" involves recent transactions involving the sale of existing nuclear units. In contrast to the units built in the 1960's and 70's (several of which are still operating) many nuclear units commissioned during the 1980s cost significantly more than expected. This was caused by the harsh economic and regulatory environment in which they were built. Plants under construction during the 1980s were engulfed in new design and operating requirements imposed by the Nuclear Regulatory Commission after the Three Mile Island accident. These changes often forced significant redesign and rework during construction, which resulted in schedule delays. At the same time, the United States was experiencing double-digit inflation and extremely high interest rates, which drove up the cost of all capital-intensive projects in all industries.

In states that have not restructured their electric power industries, this investment is being recovered over time from electricity consumers. In states that have restructured, the unrecovered original investment (often called a stranded cost) is typically recovered through some form of competitive transition charge. As a result, there was no need or incentive to recover the unamortized book value of a nuclear unit when it was sold as a result of a State restructuring initiative.

The second part of Mr. Joskow's comment involves construction of new nuclear power plants, which is covered, in part, in the answer to the previous question.

Private companies will invest in new nuclear power plants only if they are convinced that new nuclear plants are a sound business opportunity that, once built, will be competitive with other sources of electricity. Given the significant benefits of nuclear energy, the Federal Government should consider limited policy initiatives to stimulate companies to invest in new nuclear plants sooner and in larger numbers than they otherwise would. The policy initiatives necessary to stimulate construction of new nuclear generating capacity include:

1. Changes to the tax laws to reduce the investment risk associated with new nuclear plant construction and to allow quicker recovery of capital investment, including such techniques as accelerated depreciation, an investment tax credit and, possibly, access to State tax-exempt bond financing.

2. Creation of a government/industry partnership to pursue two short-term objectives: resolving technical and/or economic issues associated with the new nuclear plant designs, and validating the new licensing process—verifying that it works as intended and will not place private sector investment at risk. This initiative will require a modest additional Federal investment in nuclear energy research and development.

3. Amendments to update the Atomic Energy Act so that the NRC is positioned to meet the challenges of the 21st century. This includes removing the statutory requirement that NRC conduct antitrust reviews of applications to build new nuclear plants; removing the statutory prohibition on foreign ownership of U.S. commercial nuclear power plants; and revisions to ensure that small, modular nuclear reactors and large reactors are subject to comparable liability under the Price-Anderson Act's secondary protection scheme.

4. Renewal of the Price-Anderson Act.

Question 7. The industry now claims to be operating at much higher efficiency levels. Aren't these levels what the industry promised they would be able to offer, but failed to meet in the past? What were the major causes of the past efficiency problems? Can we expect this performance trend to continue as the plants age or are relicensed, or will we see a return to the low efficiency levels that plagued the industry?

In 2000, the industry average capacity factor was nearly 90 percent, a record high. The electricity output from U.S. nuclear power plants increased by approximately 23 percent during the 1990s—equivalent to the output from 22 new 1,000 megawatt plants. This improved performance resulted from a combination of a number of different factors, including reduction in outage duration, personnel training and experience, sharing and applying plant operating experience, and application of new technology. In effect, the industry has progressed through a natural learning curve to this record level of performance.

The industry expects the improving performance trend to continue, although it will eventually reach an upper limit, expected to be an industrywide average capacity factor approximately 92–95 percent. This is due to the fact that refueling the reactors requires outages, and those periods are nearing optimum achievable duration. The industry does not expect an adverse impact on capacity factors as plants age because many of the key components are replaced or refurbished on a regular basis as part of predictive and preventive maintenance programs.

Question 8. How much additional power could be generated from today's nuclear power plants through efficiency improvement? Does the NRC's relicensing process encourage such steps? How? If not, why not?

Response. The industry estimates that the equivalent of approximately 10,000 megawatts of capacity can be gained from the 103 nuclear units now operating through (1) further improvement in capacity factors, and (2) power uprates to existing plants.

NEI believes that there is potential for additional efficiency from plant designs. An important program in this area is the Nuclear Energy Optimization Program (NEPO), a research and development program administered by the Department of Energy. NEPO is a cost-shared program, jointly funded by Congress and the nation's nuclear utilities, to address high-priority technical issues and opportunities facing today's currently operating nuclear energy plants. These issues include opportunities for reliability and efficiency improvements through power uprates, longer fuel cycles and greater reliance on digital technologies.

NEPO was first proposed by the Department of Energy for FY 2000 and received $5 million from Congress. This year, the Bush Administration has recommended that NEPO once again receive $5 million.

NEI welcomes and commends Congress and the Administration for their support for this program. As was noted by William D. Magwood IV, the Director of the Office of Nuclear Energy, Science and Technology at the Department of Energy, "by 1998, all of [our Nation's] nuclear energy research and development programs had been terminated and policies were enacted that discouraged the use of nuclear energy or placed it at a competitive disadvantage." With the funding of NEPO and other nuclear research initiatives, Congress is once again beginning to recognize the importance of investing in nuclear research.

The NRC's license renewal process focuses solely on the safety aspects of the extended term of operation. To encourage improvements in efficiency is beyond the Commission's charter. The agency does review power uprate requests, and the Commission has recently directed the NRC staff to give high priority to the review of such requests in light of potential electricity shortages affecting different areas of the country.

NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC

Memorandum to: Chairman Meserve, Commissioner Dicus, Commissioner Diaz, Commissioner McGaffigan, Commissioner Merrifield

From: J. Hopenfeld, Engineering Research Application Branch, Division of Engineering Technology, Office of Nuclear Regulatory Research

Subject: Differing Professional Opinion On Steam Generator Tube Integrity Issues

It is now almost 10 years since I originally raised several serious safety issues concerning the NRC practice of permitting excessively degraded steam generators tubes to remain in service during plant operations. This practice while benefiting the nuclear industry, has had a serious negative potential impact on public safety. After many and continuing attempts by NRC management to ignore these DPO issues, they remain unresolved. As demonstrated by the Indian Point 2 (IP2) accident, excessively degraded tubes continue to threaten public safety.

Blatantly disregarding the recent ACRS findings (items 1–9 below) the staff granted South Texas 2 relief on March 8, 2001.

This memo is to request that you take the appropriate actions and instruct PWR plants to plug all tubes that exceeded 2 volts at the beginning of the last fuel cycle. These plants are in violation of 10 CFR PART 100 and present an unacceptable safety risk. Further regulatory relief under GL95–05 should be suspended until all the ACRS safety concerns are addressed.

During the past 10 years, the NRC has expended inordinate resources on my DPO safety issues and has publicly claimed that they have been properly addressed. The new ACRS findings, NUREG–1750, clearly indicate that the staff contentions were flawed and misleading, and that the allocated resources have been wasted.

The ACRS had concluded last November that the staff position on the issues raised by the DPO is indefensible. Accordingly, the Executive Director for Operations, EDO, was requested to resolve these issues and report the outcome to the ACRS. Instead, the EDO merely instructed the divisions of RES and NRR to draft a new action plan and closed the DPO. Closing the DPO without specifying how it will be resolved is a clear violation of Management Directive (MD) 10.159(C). The EDO's latest action compounds previous violations of MD 10.159, making a sham

of the entire process of encouraging employees to raise safety concerns. The NTEU union filed a grievance on my behalf to keep the DPO open until it is resolved.

The EDO has already tried before, and failed to cause the staff to address adequately the DPO issues. In a memo to me dated May 1, 1996, the EDO stated that, "the staff would undertake 'a vigorous research' program to investigate steam generator material behavior, adequacy of crack detection and analysis methods, behavior of steam generators under selected severe accidents scenarios, and improved understanding of iodine spiking in regard to radiological consequence, as recommended by the ACRS regard to your DPO."

Ten years of "vigorous research" clearly did not produce results that can be used to grant regulatory reliefs. These results only reflect technical ignorance and incompetence. Nevertheless, the EDO now plans to invest additional funds on "research". This practice of spending money on research for the ostensible purpose of masking regulatory inaction should be stopped.

The transcripts from the ACRS hearings and the following quotations from NUREG–1750 clearly demonstrate the poor state of knowledge at the NRC regarding steam generator safety issues.

1. "The staff has not adopted a technically defensible position on the choice of iodine spiking factor to be used on the analysis of design for compliance with requirements of 10 CFR Part 100 or General Design Criteria 19."

2. "The staff need to develop a defensible analysis of the uncertainties in its risk assessment, including uncertainties in its assessments of human error probabilities" (during design basis accidents.)

3. "The staff has not developed persuasive arguments to show that steam generator tubes will remain intact under the conditions of risk-important accidents which the reactor coolant remain pressurized."

4. "The Ad-Hoc Subcommittee found that the staff did not have a technically defensible understanding of these processes to assess adequately the potential for progression of damage of steam generator tubes."

5. "The Ad-Hoc Subcommittee did not feel that the staff has developed an adequate understanding of how movements of the tube support plate during an event could damage the tubes."

6. "The Subcommittee did not attempt to reach conclusions concerning occasions when staff granted exemptions to these criteria (1 & 2 V) except to note that these exemptions should have been accompanied by more complete risk analysis."

7. "The databases for 7/8" tubes need to be greatly improved to be useful."

8. "This issue (tube shearing during depressurization), at the current level of understanding cannot be used to judge the adequacy of the alternative repair criteria described in GL–9545."

9. "The issue of the possible evolution of severe accidents to involve gross failure of steam generator tubes and bypass of the containment is not yet resolved."

The EDO's memorandum to me dated March 5, 2001, misrepresented the ACRS findings by stating that the ACRS "found that no immediate regulatory actions are necessary." There is no reference in the ACRS report (NUREG–1750) to such findings. It is difficult to comprehend how anyone, even with minimal engineering background and knowledge of reactor operation, could conclude that the ACRS concerns do not raise serious safety issues that require immediate actions. Nevertheless, the EDO decided that these concerns can be resolved with additional research.

I disagree with the ACRS, to a degree, that the staff showed an inadequate understanding of the DPO issues. The staff has no understanding in certain major issues of the DPO. Given an environment where technical peer reviews do not exist, where staff with inadequate training is assigned to unfamiliar tasks, and where research results are preselected by management, it would be surprising if the staff had found an adequate resolution of the safety issues.

If the EDO believes that all that is required to resolve the ACRS concerns is additional research he is poorly informed concerning of how research is conducted at the NRC. In 1990, a prominent scientist, Dr. Novak Zuber told the American Nuclear Society at an award ceremony (Inside NRC, Nov 19, 1990) that the NRC conducts research in a manner which completely precludes the resolution of safety issues. What he said then is equally true today, "This (NRC) method of resolving the issue claims victory by waving arms, by twisting arms. However there is no resolution of the technical issues, and the problem is not solved, this problem will come up again next year . . . because it is not solved."

Technical solutions which are not favorable to the industry are set aside and are declared by management as "solved". Because the management is unwilling to confront the nuclear industry, staffers are afraid to express their concerns and must communicate by whispers in fear that they will be marked as "enemies" and their careers destroyed.

Last November the South Texas Project informed the staff that they would suffer a substantial financial loss if they had to plug tubes in South Texas Unit 2 beyond the 2V limit. Even though the ACRS concluded that leaving tubes beyond the 2V limit may not be conservative and South Texas did not properly address support plate movement and vibrations during depressurization, the staff quickly granted the licensees request.

The disregard of the ACRS findings and the approval of the South Texas Unit 2 request sends a clear signal to the nuclear industry: under the guise of "risk informed regulations", there is no need to have a valid and defensible technical position because regulatory relief is always granted when requested. Any rationale, even if it violates the basic laws of physics, can serve as a justification for requesting relief. Financial impact of the relief takes precedence over public safety.

Steam generators were originally sold to the utilities with the understanding that they would operate acceptably within design parameters for the lifetime of the plant. Because of inadequate and improper material selection, this expectation has never been fulfilled and some steam generators have been replaced after only a few years of service. U.S. plants alone have experienced 11 steam generator tube failure accidents, which can be traced to poor design and lack of meaningful NRC oversight. Additional, and possibly catastrophic, steam generator tube failure accidents can be expected in the future since many nuclear power plants will be re-licensed for another 20 years.

The nuclear industry, however, has done essentially nothing to seriously address the safety issue. Licensees have demonstrated that their main goal is to continue using severely degraded steam generators as long as they want to do so. The NRC has been unwilling to insist that safety take priority over economics.

My DPO defined the main safety issues that should be addressed before relaxing the existing rules, for utilizing steam generators to the maximum extent possible without endangering the pubic. While the DPO failed to attain this goal, for 10 years it has kept the public informed of the identified technical problems with severely degraded steam generator tubes. On at least one occasion, against NRC wishes, the DPO with public help, was instrumental in preventing severely degraded steam generators from being returned to service.

The NRC practices regarding steam generators contributed significantly to the recent IP2 accident. Fortunately this accident did not have significant safety consequences, it was, however, a serious precursor to the type of accidents which are described by the DPO. The NRC takes the unacceptable position that if the DPO accidents have not occurred they will not occur in the future.

The DPO has served as a reminder to the NRC that it can be held accountable for catastrophes that may follow steam generator tube failures. To remove this constant reminder, the NRC has used various methods in disregard of its own regulations: personal retaliations, attempts to select an unqualified DPO review panel, arm twisting (causing the resignation of one member from that panel), and a refusal to appoint an unbiased outside panel.

Though the ACRS findings apparently were not expected and could not be ignored, no efforts are being spared to minimize and obscure the findings. Regrettably, this continues the NRC culture of failing to keep the public informed of the danger to them from not removing severely degraded steam generators from service.

STATEMENT OF DAVID LOCHBAUM, NUCLEAR SAFETY ENGINEER, UNION OF CONCERNED SCIENTISTS

My name is David Lochbaum. I have been the nuclear safety engineer for the Union of Concerned Scientists (UCS) since October 1996. Prior to joining UCS, I spent more than 17 years in the industry on the startup and operation of nuclear power plants. UCS, established in 1969, seeks to ensure that all people have clean air, energy and transportation, as well as food that is produced in a safe and sustainable manner. We have worked on nuclear plant safety issues for nearly 30 years. In fact, far too many of the safety issues that I work on today were also worked on by my predecessor, Robert Pollard, and his predecessors, Daniel Ford and Henry Kendall. This experience convinces us that the United States should not consider an expanded role for nuclear power until we achieve something that we have never had—namely, a consistently effective regulator.

The Nuclear Regulatory Commission (NRC) has exclusive responsibility for regulating safety at U.S. nuclear power plants. That the last U.S. reactor meltdown happened 22 years ago (Three Mile Island) is circumstantial evidence that the NRC is not always an inept regulator. On the other hand, there is mounting circumstantial evidence in areas such as nuclear plant license renewal, steam generator tube crack-

ing, risk-informed regulation, and nuclear plant security indicating that the NRC is not always an effective regulator either. These warning signs are described in the following sections.

NUCLEAR PLANT LICENSE RENEWAL

The NRC currently approves a 20-year extension to the original 40-year license for a nuclear plant after its owner "demonstrates that a nuclear power plant facility's structures and components requiring aging management review in accordance with §54.21(a) for license renewal have been identified and that the effects of aging on the functionality of such structures and components will be managed to maintain the CLB [current licensing bases] such that there is an acceptable level of safety during the period of extended operation."[1] In theory, this demonstration seems like a solid basis for continued safe operation. In reality, this demonstration amounts to little more than a paperwork exercise that is frequently contradicted by actual experience. Since the beginning of the 21st century, at least eight nuclear power plants have been forced to shut down due to equipment failures caused by aging:

1. March 7, 2000: The owner reported that Nine Mile Point Unit 2 in New York had automatically shut down when the system controlling the level of water over the reactor core failed. The owner attributed the failure as "Specifically, the manual-tracking card failed to provide an output signal when the feedwater master controller was switched from automatic to manual mode of operation The manual-tracking card failed due to *aging*." [emphasis added]

2. March 14, 2000: The owner reported that Catawba Unit 1 in South Carolina had automatically shut down due to an inadvertent electrical ground problem. The owner reported "A detailed failure analysis determined that the root cause of the connector failure was the misapplication of the connector insert insulating material which is made of neoprene. . . . The neoprene insert at the failure point on the connector exhibits signs of *accelerated aging* [emphasis added]. The inserts are hardened and there are charred deposits on the end of the inserts which are indications of electrical tracking."

3. March 17, 2000: The owner reported that Indian Point Unit 2 in New York had been forced to declare an emergency condition and shut down after a steam generator tube failed and resulted in approximately 19,197 gallons leaking from the reactor coolant system. The owner stated "Preliminary analysis indicates that the cause of the tube failure is primary water stress corrosion cracking (PWSCC)" [i.e., aging].

4. March 27, 2000: The owner reported that Catawba Unit 2 in South Carolina had automatically shut down due to an inadvertent electrical ground problem. The owner reported "A detailed failure analysis determined that the root cause of the connector failure was the misapplication of the connector insert insulating material which is made of neoprene. . . . The neoprene insert at the failure point on the connector exhibits signs of *accelerated aging* [emphasis added]. The inserts are hardened and there are charred deposits on the end of the inserts which are indications of electrical tracking."

5. September 12, 2000: The owner reported that Oyster Creek in New Jersey had been forced to shut down because a system needed to provide containment integrity had failed a periodic test. The owner determined "The cause of the degradation in Secondary Containment was *age-related degradation* [emphasis added] of the automatic ventilation exhaust valve seals."

6. September 27, 2000: The NRC reported that Diablo Canyon Unit 1 in California had automatically shut down after an electrical transformer failed and interrupted the supply of electricity to the reactor coolant pumps. The NRC stated "The licensee's evaluation concluded that a center bus bar overheated at a splice joint, which caused a polyvinyl chloride boot insulator over the splice joint to smoke. Eventually, heat-induced failure of fiberglass insulation on adjacent phases resulted in phase-to-phase arcing" [i.e., aging].

7. February 16, 2001: The owner reported that North Anna Unit 2 in Virginia had been forced to shut down due to leakage exceeding 10 gallons per minute from the reactor coolant system. The owner determined "The cause of the stem packing material failure below the lantern ring is attributed to *aging*" [emphasis added].

8. April 2, 2001: The owner reported that San Onofre Unit 3 in California automatically shut down after an electrical breaker failed and started a fire. The failed breaker was reportedly 25 years old and scheduled for inspection next year. The owner "will implement modifications to appropriate *preventative maintenance* [emphasis added] procedures to address the apparent failure causes."

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[1] Part 54, Requirements for Renewal of Operating Licenses for Nuclear Power Plants, of Title 10 of the Code of Federal Regulations.

Aging management programs are intended to monitor the condition of equipment and structures and implement repairs or replacements when necessary to prevent failures. The cited aging-related failures, occurring about once every 60 days, indicate beyond reasonable doubt that the aging management programs are inadequate because they are *not* preventing equipment failures. The NRC must ascertain the effectiveness of aging management programs—not merely the scope of these programs—*before* granting license extensions.

STEAM GENERATOR TUBE CRACKING

Dr. Joram Hopenfeld, who recently retired from the NRC staff, raised concerns about the integrity of steam generator tubes to his management nearly 10 year ago. The agency—which steadfastly claims that safety is its top priority—essentially ignored them until an accident last year at Indian Point 2. The ensuing public outcry and congressional attention resulting from that accident, which was initiated when a cracked steam generator tube failed, forced the NRC to dust off Hopenfeld's concerns and finally look into them. The NRC asked its ACRS to evaluate the decade-old concerns.

The NRC's Advisory Committee on Reactor Safeguards (ACRS) issued a report in February 2001.[2] The ACRS substantiated many of Dr. Hopenfeld's concerns. For example, the ACRS concluded:

- "The techniques [used to look for cracked steam generator tubes] are not nearly so reliable for determining the depth of a crack, and in particular, whether a crack penetrates through 40 percent of the tube wall thickness." [NRC's regulations do not allow a nuclear plant to startup with any steam generator tube cracked more than 40 percent of its wall thickness, but the methods used to inspect the tubes for cracks cannot reliably determine the depth of cracks.]
- "The NRC staff acknowledged that there would be some possibility that cracks of objectionable depth might be overlooked and left in the steam generator for an additional operating cycle." [Exactly what actually happened at Indian Point 2 to cause last year's accident.]
- "Both the [NRC] staff and the author of the DPO [Dr. Hopenfeld] agree that the alternative repair criteria [used by the NRC staff to allow nuclear plants to continue operating with steam generator tubes known to be cracked] increase the probability of larger primary-to-secondary flows during the MSLB [main steam line break] and SGTR [steam generator tube rupture] accidents."
- "The [ACRS] also finds that this contention of the DPO [namely, that an accident at a nuclear plant with cracked steam generator tubes could cause those tubes to completely break] has merit and deserves investigation."
- "This seems to be a plausible contention [that an accident at a nuclear plant with cracked steam generator tubes could widen the cracks and result in larger leakage], and the staff has not produced analyses or test results to refute it."
- "The [ACRS] concluded that the issue of the possible evolution of severe accident to involve gross failure of steam generator tubes and bypass of the containment is not yet resolved [and] that the issue needs consideration regardless of the criteria adopted for the repair and replacement of steam generator tubes."
- "Data available to the [ACRS] suggest that the constant probability of detection [of cracked steam generator tubes] adopted by the NRC staff is nonconservative for flaws producing voltage signals less than about 0.7 volts." [In other words, the NRC staff assumes that methods used to find cracked tubes are much better than the data shows them to be.]
- "The [ACRS] was unable to identify defensible technical bases for the [NRC] staff decisions to not consider the correlation of the iodine spiking factor with initial iodine concentration [when evaluating the potential offsite radiation dose consequences from accidents involving cracked steam generator tubes]."
- "The [ACRS] found that the [NRC] staff did not have a technically defensible understanding of these processes to assess adequately the potential for procession of damage to steam generator tubes." [In other words, the NRC staff has no sound basis for arguing that one broken tube will not cascade and cause the failures of other tubes.]
- "The [NRC] staff has not developed persuasive arguments to show that steam generator tubes will remain intact under conditions of risk-important accidents in which the reactor coolant system remains pressurized. The current

[2]Advisory Committee on Reactor Safeguards, Nuclear Regulatory Commission, "Voltage-Based Alternative Repair Criteria," NUREG–1740 (Washington, DC: February 2001).

analyses dealing with loop seals in the coolant system are not yet adequate risk assessments."

• "In developing assessments of risk concerning these design basis accidents, the [NRC] staff must consider the probabilities of multiple tube ruptures until adequate technical arguments have been developed to show damage progression is improbable." [In other words, the risk studies to date, which only consider failure of a single tube, may understate the true risk and therefore should not be relied upon.]

The concerns raised by Dr. Hopenfeld are extremely important safety issues. As the ACRS stated:

• "Steam generators constitute more than 50 percent of the surface area of the primary pressure boundary in a pressurized water reactor."

• "Unlike other parts of the reactor pressure boundary, the barrier to fission product release provided by the steam generator tubes is not reinforced by the reactor containment as an additional barrier."

• "Leakage of primary coolant through openings in the steam generator tubes could deplete the inventory of water available for the long-term cooling of the core in the event of an accident."

In the decade since Dr. Hopenfeld first raised his safety concerns, the NRC has allowed many nuclear plants to continue operating nuclear power plants with literally thousands of steam generator tubes known to be cracked. The ACRS concluded that the NRC staff made these regulatory decisions using incomplete and inaccurate information. After receiving the ACRS's report, the NRC staff considered Hopenfeld's concerns "resolved" even though it had taken no action to address the numerous recommendations in the ACRS report (enclosure 1).

The NRC must REALLY resolve Dr. Hopenfeld's concerns as soon as possible. In the interim, the NRC must stop making decisions affecting the lives of millions of Americans when it lacks "defensible technical bases."

RISK-INFORMED REGULATION

Two of the NRC's four strategic goals are to maintain safety and to reduce unnecessary regulatory burden. The agency attempts to define "unnecessary" using plant-specific risk studies that purportedly draw a nice clean line between what is necessary and what is not. But UCS released a report titled "Nuclear Plant Risk Studies: Failing the Grade" last August detailing numerous flaws in the publicly available plant-specific risk studies. Among other flaws, we compared the risk study results for three sets of nearly identical plants and found that they varied widely—not because the risks were that disparate but because different assumptions and methods were used. Consequently, it is extraordinarily easy to move that nice clean line simply by tweaking a few input assumptions and have a burden appear as either necessary or unnecessary.

For example, the FitzPatrick nuclear plant in New York has a problem three or 4 years ago with a valve that must open following a certain accident to provide cooling flow to the reactor core. But the valve's motor did not develop sufficient thrust to move the valve against the high pressure that would occur if that accident happened. Fixing the valve was therefore a very necessary burden. Yet the plant's owner went back to the risk study and re-calculated the risk from that accident happening concurrently with a complete failure of the electrical grid and adjusted the line until the burden became "unnecessary." This example is not sharpening one's pencil because the accident in question happens most frequently when the electrical grid remains available. Thus, this vital safety system would not have functioned properly for the most likely accident scenario.[3]

More recently, the NRC staff allowed Fermi Unit 2 in Michigan to continue operating after the company broke one of its emergency diesel generator due to either incompetence or negligence. The company submitted a risk study to the NRC staff that showed the continued operation increased the threat of an accident. But the NRC staff discounted that quantified threat by saying that the unquantified threat from shutting down and then restarting the nuclear reactor would somehow pose an even larger threat. This NRC decision contradicts its own regulations, policies, and procedures and UCS has asked the NRC's Inspector General to investigate this matter (enclosure 2).

[3] Fortunately, this unsafe condition has been remedied. The plant's owner fixed the valve motor at the next scheduled refueling outage. The bogus risk study was used to allow the plant to continue running with the non-functional valve for months. The plant's operating license as granted by the NRC only permitted operation for up to 7 days with this vital safety equipment inoperable.

The plant-specific risk studies that UCS reviewed for our report are nearly 10 years old, but they are the most recent risk studies that are publicly available. The NRC is allowing plant owners to reduce the testing frequency for emergency equipment or to continue operating with degraded equipment based on results from more recent risk studies. The previously cited ACRS report on Hopenfeld's steam generator tube integrity concerns indicates that the more recent risk studies remain inaccurate and incomplete. Members of the public and organizations like UCS cannot challenge these regulatory decisions because we lack access to the risk studies. The NRC's own regulations, policies, and procedures require such information to be publicly available, but it is not. And the agency continues to make regulatory decisions affecting the lives of millions of Americans in a vacuum. The NRC must require the flaws in the risk studies to be corrected AND make sufficient information about the corrected risk studies publicly available.

NUCLEAR PLANT SECURITY

The NRC's handling of physical security at nuclear reactors is another example of regulatory ineffectiveness. The NRC began force-on-force tests of security preparedness at nuclear power plants in the early 1990's. These tests pit a handful of simulated intruders against a plant's physical defenses and squadrons of armed security personnel. By 1998, these tests had revealed significant security weaknesses in about 47 percent of the plants tested. The NRC quietly discontinued the testing, but the ensuing public outrage forced the agency to re-institute the tests. Since the tests have been resumed, about 47 percent of the plants continue to have significant security flaws revealed. Last year, force-on-force tests at the Waterford plant in Louisiana and the Quad Cities plant in Illinois demonstrated serious security problems that warranted extensive repairs and upgrades. The owner of the Waterford spent more than $2 million fixing its inadequate security system.

Having been foiled in its attempt to secretly deep-six the security tests, the agency resorted to Plan B in which they will allow the plant owners to conduct the tests themselves, grade the tests themselves, and simply mail in the scores—virtually guaranteed to be high marks—to the NRC. If someone like Timothy McVeigh drove to a nuclear power plant with intentions of causing harm, the people living near that plant would better protected by security scoring 85 percent on a real test than 100 or even 110 percent on an open-book, take-home, self-scored test. The public deserves and must get that better protection than that provided by artificially inflated security test scores.

NEW NUCLEAR PLANTS

A new nuclear technology called the pebble-bed modular reactor is getting considerable mention as the type of nuclear reactor most likely to be built in the United States in the future. The pebble-bed reactor does offer certain safety advantages—at least, on paper. Proponents claim that the pebble-bed reactor cannot experience the meltdown-type accident as occurred at Three Mile Island in 1979. Perhaps, but can the pebble-bed reactor, which will use more graphite in each reactor module than is presently used in all existing U.S. nuclear power plants combined, can on fire and burn as happened at Windscale in 1957 and Chernobyl in 1986? Can plant workers, either by mistake or by design, trigger an accident as occurred at the SL–1 nuclear reactor in 1961 and Dresden Unit 3 in 1974 and Browns Ferry in 1975? Can some unexpected component failure cause fuel damage, as occurred at Fermi Unit 1 in 1966?

The pebble-bed reactor is rumored to be competitive with other energy technologies. It appears from a preliminary design review that the proposed reactor achieves its economic advantages by replacing the steel-lined, reinforced-concrete containment structures used for our existing nuclear plants with a far less robust enclosure building. The NRC's own Advisory Committee on Reactor Safeguards characterized this as "a major safety tradeoff."

The safety problem with the proposed "containment-lite" pebble-bed reactor design Is compounded by the existing security weaknesses. Imagine the consequences from a fertilizer truck bomb detonated next to a "containment-lite" reactor with millions of curies of lethal radioactivity to contaminate the environment for many decades. That would truly be a nuclear nightmare.

Cost projections by the nuclear industry must be taken with a grain of salt, if not an entire salt shaker. According to the U.S. Department of Energy, the actual construction costs for 75 nuclear power plants started between 1966 and 1977 were

more than three times higher than their estimated costs.[4] Thus, claims that the projected costs of electricity from a proposed pebble-bed reactor are competitive with the actual costs of electricity from operating renewable energy technologies must be viewed with skepticism.

It cannot be overemphasized that a facility like the proposed pebble-bed modular reactor has never been constructed or operated in the world. Consequently, its expected performance characteristics are highly speculative. It would not be prudent at this time to place undue reliance on a risky technology with unproven safety performance. Nuclear experiments belong in the laboratory, not within the U.S. electricity marketplace.

CONCLUSIONS AND RECOMMENDATIONS

Nuclear power plants are inherently dangerous. If nuclear power is to play an expanded role in the future, it is imperative that the Nuclear Regulatory Commission become a consistently effective regulator. UCS believes that this goal is attainable. The Maintenance Rule (10 CFR 50.63) and the revised reactor oversight process demonstrate that the agency is capable of effective regulation. That capability must be extended across all of the NRC's oversight functions and consistently sustained. This transformation may require that the agency receive additional resources, particularly during the transformation phase. Because the agency is currently a fee-based agency, it may require legislative changes to supplement the existing resources with taxpayer money.

Failing to reform the Nuclear Regulatory Commission could have tragic consequences. As reported in The Wall Street Journal (enclosure 3), the 1986 accident at the Chernobyl nuclear plant cost the former Soviet Union several times the net benefits from all Soviet reactors ever operated. The price tag for the accident was placed at 170 to 215 billion rubles while the net benefits from every Soviet nuclear power plant was only 10 to 50 billion rubles. With the price of failure so very high, it is absolutely imperative that the Nuclear Regulatory Commission be a consistently—rather than occasionally—effective regulator.

If Congress wants an expanded role for nuclear power, it must provide the NRC with the resources needed for the agency to implement consistently effective regulatory programs and must also oversee the agency's reform efforts to verify that they are successful.

UNION OF CONCERNED SCIENTISTS,
April 13, 2001.

MR. HUBERT BELL, *Inspector General,*
U.S. Nuclear Regulatory Commission,
Washington, DC.

Subject: Allegation of Improper NRC Staff Action

DEAR MR. BELL: By letter dated March 29, 2001 (enclosure 1), NRC Region III documented their granting of enforcement discretion to the Detroit Edison Company to allow the Fermi 2 reactor to continue operating for an additional 7-day period with one of its emergency diesel generators broken. After reviewing this letter and the company's letter dated March 26, 2001, (enclosure 2) that requested it, I concluded that the NRC staff did not follow the instructions in NRC Inspection Manual Part 9900, "Operations—Notices of Enforcement Discretion" (enclosure 3) and in NRC Regulatory Guide 1.177, An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications" (enclosure 4).

If my conclusion is correct, then it appears that the NRC staff should *not* have granted this enforcement discretion and subjected the people living near the facility to undue risks. I did not survey other notices of enforcement discretion to determine if the Fermi 2 case is an isolated one or the tip of an iceberg.

On behalf of the Union of Concerned Scientists, I respectfully request that the Office of the Inspector General investigate this Notice of Enforcement Discretion. If your investigators substantiate my conclusion, I would additionally ask that your investigation examine other recent Notices of Enforcement Discretion to determine if the problem is isolated or pervasive.

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[4] United States Department of Energy, "Analysis of Nuclear Plant Construction Costs," DOE/EIA–0485 (Washington, DC: 1985).

BACKGROUND

By letter dated March 29, 2001, the NRC's Region III office issued a Notice of Enforcement Discretion to Detroit Edison allowing the Fermi 2 reactor to continue operating for up to seven more days with a broken emergency diesel generator. According to the March 26th letter submitted to the NRC by Detroit Edison, the emergency diesel generator came to be broken as follows:

> The outboard bearing failed suddenly and catastrophically during an endurance run recently when operated to fulfill periodic TS [Technical Specification] surveillance requirements.
>
> EDG–14 was started and loaded for the purpose of performing the 24-hour endurance surveillance testing per TS [Technical Specification] Surveillance Requirement (SR) 3.8.1.13, on March 21, 2001 at 1011 hours. At 2206 hours, a generator trouble alarm was received. It was noted that the EDG 14 generator outboard bearing temperature was 228° degrees F and rising rapidly. The EDG 14 output breaker was opened, and EDG 14 was manually tripped. One minute later, the operator reported a fire on the EDG 14 outboard bearing housing.

Detroit Edison stated that the emergency diesel generator broke because:

> The root cause has been determined to be a lower than adequate oil level in the bearing housing. The oil level was below the vendor recommended minimum value of six inches below the centerline of the generator shaft. The actual oil level at the time of the event was at 6⅞ inches below the centerline of the generator shaft, ⅞ inch below the recommended minimum.
>
> The operator indicated that the oil level was at the bottom of the "green band."

The company explained how the oil level came to be ⅞ inch (0.875 inch) lower than the recommended minimum:

> A stiffener plate was added to the outboard end of the generator housing [in 1984] to reduce axial vibration on EDG 14 only. This led to a modification of the oil sight glass piping. It is believed that the oil level sight glass was incorrectly lowered at that time, thus indicating higher by approximately 0.9 inches than the actual oil level in the bearing.

So the company made a mistake nearly 17 years ago. And the company reported two recent failures to identify and correct this mistake, which I will refer to as Missed Opportunity No. 1 and Missed Opportunity No. 2:

> A nonconformance report (DER) was issued [in 1997] questioning the proper oil levels for the EDG generator bearings. . . . Operator rounds sheets and the maintenance procedure were revised with the new oil level tolerances. [Missed Opportunity No. I]
>
> A site wide program for improving oil level indication installed oil level "green bands" on all EDG generator bearings [in 1999]. The green band on EDG 14 was erroneously placed too low using the tick mark that had existed since 1984, resulting in a higher apparent indication (approximately 0.9 inches) than what actually existed. Maintaining oil in the green band could result in the oil level being too low. {Missed Opportunity No. 2]

The company claimed:

> This request for enforcement discretion was unavoidable due to the sudden, rapid degradation of the affected EDG 14 bearing, approximately 12 hours into the 24-hour endurance run, and was not created by a failure to make a timely application for a license amendment.

I strongly disagree with the company's assertion of "unavoidable." The company conceded that its error in a 1984 modification was the root cause of the failure. Even if that mistake was indeed unavoidable—which seems doubtful since other plant owners have been able to modify their emergency diesel generators without breaking them—it is hard to understand how the 1997 nonconformance report specifically written on oil levels and the 1999 green band effort failed to identify the error. Had the company complied with its legal obligations under 10 CFR 50 Appendix B in 1984, in 1997, or in 1999—just one act of compliance over a 15-year period—the failure would have been very avoidable.

The company's point that their request "was not created by a failure to make a timely application for a license amendment" is irrelevant. They are not seeking a license amendment as a remedy. Instead, they sought more time to fix the broken emergency diesel generator that directly resulted from their mistake in 1984 and oversights in 1997 and 1999. It was very clearly a failure to take timely corrective actions.

The NRC staff compounded and supplemented the mistakes made by Detroit Edison by granting the requested enforcement discretion contrary to the requirements of Inspection Manual Part 9900 and Reg Guide 1.177. Section B of Inspection Manual Part 9900 states:

> Careful regulatory scrutiny should be given to any deviation from the required actions of the TS [Technical Specifications] or other license conditions for circumstances involving violations, poor planning, repeated NOED request for the same reasons, or some similarly avoidable situation.

As described previously, the company conceded that it had introduced the flaw to the emergency diesel generator in 1984 and failed to correct it during specific, targeted examinations in 1997 and 1999. Therefore, it implicitly admitted to three separate and distinct violations of 10 CFR 50 Appendix B. Absent these repeated violations, there is no hint, yet alone evidence, that the emergency diesel generator would have failed during the March 2001 test. Clearly, this was an avoidable failure that wasn't avoided due to the company's own incompetence which the NRC staff rewarded with enforcement discretion.

Paragraph 2.1 of Section B of Inspection Manual Part 9900 states:

> Granting of this type of an NOED [regular NOED as opposed to severe weather-related NOED] shall not involve an increase in radiological risk.

Note that this requirement does not allow a minimal or negligible increase in risk. This criterion permits *no* increase in radiological risk. 'No' means 'no.'

Detroit Edison conducted a plant-specific risk assessment for operating the reactor for 14 days with EDG 14 broken compared to the 7 days permitted by the Technical Specifications. The results of that assessment are documented in the company's March 26th letter to the NRC and are parroted by the NRC staff in its March 29th letter:

> The results showed an incremental conditional core damage probability of 2.08E–7 and an incremental conditional large early release probability of 3.66E–8.

Thus, both the company and the NRC explicitly reported an increase in radiological risk. But the NRC approved the enforcement discretion. Apparently, 'no' means 'maybe' to the NRC staff.

It appears that the NRC staff justified this very clear violation of the explicit criterion in NRC Inspection Manual Part 9900 on this basis:

> Your submittal [i.e., Detroit Edison's March 26th letter] also stated that eliminating the plant shutdown required by the Technical Specifications would eliminate consequent transitional risk associated with a shutdown and startup of the plant, offsetting the risk associated with the increased time of the diesel outage and resulting in a minimal effect on plant safety.

Neither the staff's letter nor the company's letter provides a qualitative assessment of the alleged transitional risk. Consequently, the quantitative assessment showing a risk increase is opposed by a subjective, undocumented, non-qualitative, non-quantitate assessment (i.e., hand-waving). Paragraph 4.0 of Section B of NRC Inspection Manual Part 9900 states:

> The safety basis for the request, including an evaluation of the safety significance and potential consequences of the proposed course of action. This evaluation should include at least a qualitative risk assessment.

In this case, Detroit Edison submitted the results from their quantitative assessment showing an increase in both core damage probability and large early release probability. Yet the staff dismissed those results and accepted an undocumented, unreported, non-qualitative assessment by the company that shutting down and starting back up posed a greater risk.

I had a conference call with Mr. Mark Ring, Mr. Steve Reynolds, and Mr. John Grobe of the NRC Region III staff earlier this week regarding this Notice of Enforcement Discretion and its alleged justification. Mr. Grobe concurred with my observation that the purported risk from shutting down and starting up had not been quantified by the company or by the NRC staff. He explained that current probabilistic risk assessment methods are not evolved enough to evaluate all the complex variables associated with shutting down and restarting a reactor. If that is true, how can the NRC staff have confidence that this unquantifiable risk is less the quantifiable risk from continuing to operate the reactor with a broken diesel generator?

Section A of Reg Guide 1.177 states:

> PRA [probabilistic risk assessment] evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

The results from the quantitative assessment submitted by Detroit Edison and parroted by the NRC staff simply do not satisfy either the spirit or the letter of the "appropriate supporting data should be publicly available for review" standard. In addition, there was absolutely no information provided on the alleged transitional risk to assess whether it satisfied the "as realistic as practicable." For all I know, the company based its statement on a guess. Maybe it was even a hunch. Perhaps they used a round or two of "paper/rock/scissor." But it very clearly was not "at least a qualitative assessment" with "appropriate supporting data" "publicly available for review." And for that reason, the NRC staff should not have granted Detroit Edison's wishes. But it did.

CONCLUSIONS

(1) The failure of emergency diesel generator 14 in March 2001 was entirely avoidable if the company (a) had not made an error during a modification back in 1984, (b) had not failed to identify and fix the error while resolving a nonconformance report in 1997, and (c) had not failed to identify and fix the error while specifying proper oil levels in 1999.

(2) The failure of emergency diesel generator 14 in March 2001 resulted from repeated violations of 10 CFR 50 Appendix B by the company.

(3) The NRC staff did not exercise "careful regulatory scrutiny" for "violations . . . or some similarly avoidable situation" when it reviewed the request for enforcement discretion.

(4) The NRC staff violated NRC Inspection Manual Part 9900's criterion that "an NOED shall not involve an increase in radiological risk" because the company's only qualitative assessment reported. an increase both in core damage probability and large early release probability.

(5) The NRC staff violated NRC Inspection Manual Part 9900's criterion that the company's evaluation "should include at least a qualitative risk assessment" because the staff accepted an ill-defined, quantitative assessment that the risk from shutting down and restarting the reactor was somehow greater than the results from the qualitative risk assessment for continuing to operate the reactor with one emergency diesel generator known to be broken (since the company broke it).

(6) The NRC staff violated NRC Regulatory Guide 1.177's criterion that "appropriate supporting data should be publicly available for review" since only the results from the qualitative assessment for continuing to operate the reactor with one emergency diesel generator known to be broken are publicly available. The company's guess—or hunch—and the NRC staff's confirmatory guess—or hunch—is not publicly available.

(7) The NRC staff did not conform with NRC Inspection Manual Part 9900 and Regulatory Guide 1.177 and therefore should NOT have granted enforcement discretion in this case.

I respectfully request that your office determine if my conclusions are valid. I would be glad to meet with your staff to further explain my concerns about this matter.

Sincerely,

DAVID A. LOCHBAUM,
Nuclear Safety Engineer.

[From The Wall Street Journal, Thursday, March 29, 1990]

COST OF CHERNOBYL NUCLEAR DISASTER SOARS IN NEW STUDY—1986 REACTOR ACCIDENT DWARFS OTHER SOVIET PEACETIME CATASTROPHES

(By Richard L. Hudson, Staff Reporter)

MOSCOW—A new Soviet study concludes that continuing economic fallout from the Chernobyl nuclear accident may cost 20 times more than Moscow's prior estimates, ranking Chernobyl as the most costly catastrophe in Soviet peacetime history.

The study, by a Soviet nuclear industry economist, estimates that by the year 2000 the Chernobyl accident may cost the country 170 billion to 215 billion rubles in lost electricity production, contaminated farmland and other economic consequences. Moscow's previous estimate, which counted only the immediate cleanup costs, was 10 billion rubles.

Because the ruble isn't freely convertible, the new estimate can't be expressed accurately in Western currencies. At the official exchange rate in Moscow, it amounts to $283 billion to $358 billion. In any currency, the sum far exceeds cost estimates

for such previous Soviet disasters as the 1988 Armenian earthquake. The April 26, 1986, accident was the "the biggest socioeconomic cataclysm in [peacetime] history," the study says, adding that Chernobyl also contributed to the country's worsening economic problems.

INTERNAL DEBATE IS MOUNTING

The study supports Western speculation that Moscow initially underestimated Chernobyl's cost. But its scheduled publication in Soviet news media this year will contribute to a mounting internal debate over the accident's cleanup costs. Local government officials near the Ukranian reactor are pressing Moscow to provide 35 billion rubles in projected cleanup expenses. And the Supreme Soviet, the country's standing parliament, plans a public debate on the issue later this year.

The report was commissioned by a participant in this debate, and is thus a rare example of a Soviet special-interest group learning such Western lobbying techniques as commissioning research. The study's sponsor was the Chernobyl Union, an organization of accident survivors pressing Moscow for more aid. The economist who performed the study is Yuri Koryakin, chief economist of the Research and Development Institute of Power Engineering, a Soviet government institute that designed the Chernobyl reactor. In an interview, Mr. Koryakin said he agreed to conduct the study in the interests of promoting wider public debate about the Chernobyl accident.

Mr. Koryakin's findings will likely be contested by some Soviet officials. But to minimize official criticism, he said, his study used only information pulled from previous Soviet publications—and avoided use of any of his institute's official, non-public documents. He said, however, that he believes his study is the first anywhere in the Soviet government to attempt to add together all the direct and indirect accident costs.

Cleanup and study of the Chernobyl accident has become a major, permanent segment of Soviet industry. The accident, caused when operators lost control of a reactor, spewed radiation for days over the surrounding Ukranian, Byelorussian and Russian countryside. It forced the permanent evacuation of thousands, and contaminated about 31,000 square kilometers (12,400 square miles) of farmland and forests with long-lived radioactive cesium, strontium and other elements.

By Mr. Koryakin's estimates, the cost of losing agricultural production on the contaminated land is among the single biggest costs of Chernobyl to the Soviet economy. From 1986 to 2000, the lost land value totals 57.5 billion to 94.5 billion rubles. A few years ago, Soviet scientists were blithely forecasting a quick return to agriculture by, for instance using special breeds of cattle and switching them to imported, non-radioactive feed a few weeks before slaughter. But lately such optimistic talk has died out, leading some specialists to consider the contaminated land a total loss for at least two generations.

LOST ELECTRICITY PRODUCTION

The second-biggest economic consequence of Chernobyl, Mr. Koryakin's study says, is lost electricity production—valued at about 66.8 billion rubles through 2000. Following the accident, Soviet public opinion turned sharply against nuclear power, and Soviet authorities were forced to halt or cancel plans for 32 nuclear power reactors.

In some areas of the Soviet Union, the nuclear cutbacks have worsened power shortages. For instance, closure of two reactors in Armenia cost the Transcaucasus region 15 percent of its power supply, leading to restrictions in local electricity consumption. Also, post-accident safety projects at many of the country's other reactors will raise their average electricity costs by 0.08 kopecks a kilowatt-hour, or 9 percent, the study says.

Gradually decontaminating the countryside, evacuating people and completing other cleanup tasks may cost 35 billion to 45 billion rubles through 2000, the study says. Other costs include 3.9 billion to 5.1 billion rubles to install new safety equipment at Soviet reactors, and the loss of five billion rubles in capital invested in reactors closed after Chernobyl.

The total bill suggests that the Soviet Union may have been better off if it had never begun building nuclear reactors in the first place. Since the Soviets opened their first power reactor in 1954. Mr. Koryakin estimates, the net economic contribution of the Soviet nuclear has been 10 billion to 50 billion rubles. The sum is a measure of how much money the country saved by using cheaper, nuclear-generated electricity than more costly coal-burning plants. The Chernobyl accident costs exceed that sum by several times.

RESPONSES BY DAVID LOCHBAUM, TO ADDITIONAL QUESTIONS FROM SENATOR REID

Question 1. In your testimony, you indicated the public does not have access to risk studies that are crucial to the new reactor oversight program. Are there other problems in regard to public access to documents, staff, and Commissioner? How does the recent proposal to remove the formal hearing structure affect this?

Response. Yes, there are other problems in regard to public access to documents. On October 29, 1999, the NRC announced an electronic library for its documents.[1] The NRC stated:

> The Nuclear Regulatory Commission has begun making documents available to the public through an "electronic reading room" on the agency's website, which is accessible by computers in homes, schools, offices, and libraries, using a standard web browser.
>
> The site is "user-friendly," and contains easily understandable instructions for searching, viewing and downloading documents.

However, this "electronic reading room," called ADAMS, is neither "accessible" nor "user-friendly." In order to use the software that the NRC adopted to interface with ADAMS, users must alter the communication protocols of their computers, commonly referred to as "dropping the fire-walls." These communication protocols are intended to prevent hackers from unauthorized access to users' computer systems. Therefore, many users, particularly schools, offices, and libraries, have not "dropped the fire-walls" and cannot enter the NRC's electronic reading room.

Even if one is fortunate enough to be able to enter the electronic reading room, there are still major problems. Documents are stored in ADAMS in either PDF or TIFF format. The TIFF format is extremely large. For example, UCS downloaded a 26-page document from ADAMS earlier this week. In TIFF format, the file was over 2.4 Mb in size. Documents must be downloaded from ADAMS because the NRC's interface software does not allow single pages to be printed out. UCS had to download an entire transcript in TIFF format that was over 15 Mb in size just to be able to print out selected portions. The unnecessarily large file size means that public stakeholders cannot go to public libraries and download files to a floppy diskette (1.44 Mb maximum capacity) for later use in their homes.

At stake is not simply greater convenience. In conjunction with opening the electronic reading room, the NRC effectively closed local public document rooms across the United States by refusing to send them records. Consequently, these local public document rooms do not have records since late 1999.

In many communities, members of the public cannot access the NRC's electronic reading room and can no longer go to their local public document rooms to access contemporary documents. The NRC's actions have had the effect of barring public access to information about the nuclear facilities in their backyards.

UCS formally asked the NRC Chairman to take specific measures to offset the damage done by the shift to the inaccessible electronic reading room. For example, we asked that public comment periods be increased by 100 percent until the ADAMS problems were remedied.[2] Most public comment periods last 30 days. We asked for 30 more days to compensate for the undue burden that had been placed on the public in having to obtain documents through alternative methods. Our very reasonable request was summarily rejected. It is baffling that an agency that claims to have "improve public confidence" as one of only four strategic goals would take such a cavalier attitude.

UCS is very concerned about the proposal by the NRC to change from a formal hearing process to an informal hearing process. The informal hearing process means that the public gives up its rights to discovery and cross-examination. The NRC has stated:[3]

> In the past, workers in NRC-regulated nuclear activities and concerned citizens have raised important safety issues and, as a result, public health and safety have benefitted.

The key phrase here is "in the past." If the NRC is successful in foisting its informal hearing process on the American public, concerned citizens will have virtually no ability to raise important safety issues with the NRC. As the NRC concedes, this cannot benefit safety.

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[1] Nuclear Regulatory Commission, News Release No. 99–232, "NRC Makes Documents Available to the Public on its Website," October 29, 1999.

[2] Letter dated September 22, 2000, from David Lochbaum, Union of Concerned Scientists, to Dr. Richard A. Meserve, Chairman, Nuclear Regulatory Commission.

[3] Nuclear Regulatory Commission, "Reporting Safety Concerns," NUREG/BR–0240, Revision 1, available on the web at *http://www.nrc.gov/NRC/NUREGS/BR0240/Rl/index.html*

UCS is particularly disappointed by the approach the NRC is taking towards informal hearing processes. It wants to make informal hearings the standard, or at least to only grant formal hearings when the agency chooses. Contrast that treatment of public stakeholders with how the NRC is treating plant owners. The NRC is pursuing a number of so-called risk-informed regulatory improvements. But the NRC intends to make them voluntary so plant owners can stick with the existing regulations or adopt the new regulations—whichever they want. Why can't the NRC permit its public stakeholders to choose between formal and informal hearings as it allows plant owners to choose between prescriptive and risk-informed regulations?

Question 2. Do you expect the industry to build a new plant in the next 10 years without significant Government subsidization?

Response. While we cannot rule out the possibility of an un-subsidized nuclear plant being built, it appears more likely that subsidization will be required. UCS attended the public meeting held in late January 2001 between representatives of the Exelon Corporation and the NRC staff. Exelon asked the NRC staff to figure out how the Government could pay for the NRC's review of the pebble-bed modular reactor. This would clearly be subsidization.

During the Senate Subcommittee hearing on May 8, Mr. Oliver Kingsley of Exelon testified that it was imperative that Congress extend the Price-Anderson Act to cover new reactor designs. Currently, plant owners must obtain liability coverage up to $200 million. If an accident resulted in damages above $200 million, other plant owners could be dunned up to $10 million per reactor per year for 10 years. Payment for damages above that point (approximately $9 billion) would be up to Congress to decide whom to invoice. Obviously, plant owners would be forced to pay higher premiums if they had to cover their entire liabilities instead of only the first $200 million. This represents another subsidy requested by the industry for new reactors.

Question 3. Are there issues relating to worker fatigue and forced overtime that you believe could affect the safe operation of the nuclear power plants. Is the Commission taking steps to address those? If not, what should be done?

Response. Yes. The NRC received a petition for rulemaking dated September 28, 1999, that seeks to revise NRC's regulations to provide uniform, enforceable working hour limits. UCS formally supported, and continues to support, that petition. UCS had issued a report earlier that year[4] that documented scientific evidence that human performance is impaired by fatigue to the same, or higher degree, than by alcohol consumption. The NRC promulgated regulations, 10 CFR Part 26 or the Fitness-For-Duty rule, that ensure nuclear plant workers are not impaired by drug or alcohol usage. Yet data compiled by the Nuclear Energy Institute[5] clearly show that some plant owners require workers to become fatigued on the job. For example, there were nearly 7,000 deviations from the working hour limits at one nuclear plant in 1999 alone, or an average of nearly one deviation every hour for an entire year. On the other hand, the data also clearly show that many plant owners are able to comply with the working hour limits. So, it is possible to avoid the increased threat from fatigued workers if the NRC would simply adopt and enforce consistent working hour limits.

The NRC staff is working on the petition for rulemaking, but it is not on the fast track. Since it is only a safety issue, it must take a backseat to efforts being undertaken by the NRC staff to improve the financial performance of the nuclear fleet. The American public would be better served if the NRC Commission directed its staff to place priority on safety rather than on economics. Both are important and worthy of NRC effort, but safety should not continue to be the NRC's second priority.

STATEMENT OF OLIVER D. KINGSLEY, JR., PRESIDENT AND CHIEF NUCLEAR OFFICER; EXELON NUCLEAR, EXELON GENERATION COMPANY, LLC

Mr. Chairman and members of the subcommittee: I appreciate the invitation to appear before the subcommittee to discuss the state of the nuclear energy industry and the role that nuclear power can play in meeting America's future energy needs. My name is Oliver D. Kingsley, Jr., and I am the president and chief nuclear officer of Exelon Nuclear, the nuclear division of Exelon Generation Company.

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[4] Union of Concerned Scientists, "Overtime and Staffing Problems in the Commercial Nuclear Power Industry," March 1999.

[5] Letter dated August 29, 2000, from James W. Davis, Nuclear Energy Institute, to Glenn M. Tracy, Nuclear Regulatory Commission.

Exelon Generation is a wholly-owned subsidiary of Exelon Corporation. Exelon was formed last year by the merger of Unicom Corporation of Chicago and PECO Energy Company of Philadelphia. Exelon Generation currently owns and operates approximately 37,000 megawatts of diversified electrical generation, including 17 nuclear reactors that generate 16,970 megawatts of electricity. We have another 8,500 megawatts of non-nuclear generation under construction or development. Exelon is the largest nuclear generation operator in the country with approximately 20 percent of the nation's nuclear generation capacity, and the third largest private nuclear operator in the world. We also own 50 percent of AmerGen Energy, which is a partnership with British Energy of Edinburgh, Scotland. Amergen owns three of the 17 units in the Exelon fleet.

THE STATE OF THE INDUSTRY

The nuclear industry is receiving substantial public attention as policymakers evaluate options for maintaining a clean, safe, reliable, and low-cost energy supply for the United States. The renewed focus on nuclear energy is due to a variety of reasons:

- Nuclear has a proven track record of safe and improving operations;
- Nuclear power is economically competitive;
- Nuclear capacity is increasing, even without building new plants;
- Prospects for license extension for existing plants are positive; and
- The current regulatory environment is stable and constructive.

The nuclear energy industry is contributing safe, cost competitive, and reliable baseload power to meet the nation's energy needs, all without emitting any air pollutants or greenhouse gases associated with fossil-fired plants.

Nuclear Power is Economically Competitive

Let me highlight the current economics of nuclear power production. In our vernacular, the total cost of producing electricity from a power plant is known as the "all-in" cost. Current, well-managed nuclear plants have an all-in cost of less than 2.5 cents per kilowatt-hour (kWh). This cost compares favorably with the all-in cost for combined cycle natural gas plants at 3.5 to 4.5 cents per kilowatt-hour (assuming a gas price of $3 to $4 per million BTUs). Natural gas prices paid by electricity generators have doubled in the past year and are likely to continue to exceed historical costs. In contrast, nuclear fuel costs have been substantially less volatile. For the industry as a whole, nuclear production costs in 1999 of 1.83 cents per kilowatt-hour were lower than production costs for coal (2.07 cents per kilowatt-hour), natural gas (3.52 cents per kilowatt-hour, even prior to natural gas price spikes) or oil (3.18 cents per kilowatt-hour).

The recent crisis in California has led policymakers to focus on the need for a sound, comprehensive national energy strategy. Clearly, our national energy policy should include recognition of the important role that nuclear power has played—and will continue to play—in meeting the nation's growing energy needs and addressing clean air goals.

Nuclear Capacity is Increasing—Without Building New Plants

Even though we have not constructed any new nuclear power plants in our country in recent years, our nation's nuclear capacity is increasing. Two things are happening: we are adding capacity at existing plants and we are operating those plants more efficiently. For example, Exelon Nuclear is adding nuclear capacity through a combination of power uprates and plant modifications that will improve the efficiency of the units. Through these modifications and improved operation, Exelon Nuclear will increase net generation from its current fleet by approximately 9 million-megawatt hours by 2003, the equivalent of adding a new 1,200 megawatt plant. Our planned power uprates will be achieved at a construction cost $300–$400 per kilowatt, well under the cost of $500 to $700 per kilowatt for a new combined cycle natural gas plant, and $1,000 to $1,250 per kilowatt for new clean coal technologies. Other utilities are doing the same.

Prospects for License Extension are Positive

The long-term prospects for our nation's nuclear fleet are also positive, defying some predictions. As recently as 1997, the NRC estimated that only a fraction of currently operating reactors would seek to extend their operating licenses. Today, most observers, including NRC Chairman Meserve, predict that the vast majority of the nation's 103 operating plants will apply for 20-year license extensions. Between 2001–2003, Exelon will submit license renewal applications to the NRC for the Peach Bottom, Dresden and Quad Cities nuclear power plants, and we are reviewing the potential for license renewal for the remainder of the Exelon fleet.

With the forces of market competition reshaping the entire electricity industry and driving down the cost of electricity, nuclear power's competitiveness will continue to hinge, in part, on how well Federal regulations keep pace with industry changes.

Current Regulatory Environment is Stable and Constructive

The current regulatory environment has become more stable, timely, and predictable, and is an important contributor to improved performance of nuclear plants in the United States. This means that operators can focus more on achieving operational efficiencies and regulators can focus more on issues of safety significance. It is important to note that safety is being maintained and, in fact enhanced, as these benefits of regulatory reform are being realized. The Nuclear Regulatory Commission and this Subcommittee can claim a number of successes in their efforts to improve the nuclear regulatory environment. These include successful implementation of the NRC Reactor Oversight Process, the timely extension of operating licenses at Calvert Cliffs and Oconee, the establishment of a one-step licensing process for advanced reactors, the streamlining of the license transfer process, and the increased efficiency in processing licensing actions.

NRC Reactor Oversight Process

While Exelon Nuclear is proud of the work that we have done to improve our operations and production, we must note that many of these improvements have been facilitated by regulatory changes. A fine example of this is the NRC Reactor Oversight Process, which has created greater certainty and predictability in the regulatory environment. I want to recap some of the progress made to date while indicating areas where additional improvements are needed.

The Reactor Oversight Process (ROP) is a decided improvement over the previous process. The new approach is objective, safety-focused, predictable and more understandable to the industry and the public. In most cases the process has been demonstrated to objectively distinguish levels of safety performance and to consistently apply the prescribed levels of NRC oversight to these differing levels of performance. This safety focus of the NRC enables us to continuously sharpen our safety focus while more efficiently applying our resources to "do the right thing right the first time". This improved focus also serves to reinforce the industry's obligation to find and fix our own problems. But more importantly it places the accountability for safe and efficient operation squarely where it belongs with us, the nuclear operators.

The NRC, working closely with its stakeholders, has achieved a largely revised and vastly improved regulatory framework for NRC oversight of licensees in a short amount of time. I cannot fail to acknowledge the vital role that the Nuclear Energy Institute has played in helping the industry establish improved communications and a cooperative working relationship with the NRC. This relationship only exists as the result of proper execution of our regulatory processes combined with industry-wide continued good performance.

Both the industry and the NRC are continuing to properly prioritize and pursue process improvements that reflect the lessons learned from the initial year of implementation of the Reactor Oversight Process. An important initiative to achieve common industry performance indicators is in progress that will sharpen the focus on risk significant conditions, reduce undue burden caused by differing definitions, and address perceived concerns regarding inconsistencies.

SUSTAINING THE NUCLEAR OPTION

In addition to the progress that has been made on the previously mentioned issues, there remain many regulatory and legislative actions needed to continue this progress and set the stage for construction of new plants. In order to sustain the nuclear option we need:

- A reliable, competitive nuclear fuel market;
- Legislative and regulatory reforms;
- A stable new plant regulatory framework;
- Renewal of the Price-Anderson Act;
- Public funding for first-time costs;
- Enhanced nuclear research and development programs;
- To retain and attract top talent;
- Environmental policy must recognize the advantages of emission-free electricity; and
- Proper alignment of NRC resources.

I would be remiss if I do not mention the urgent need for the government to complete the work necessary to build a geologic repository for used nuclear fuel. Until the Federal Government can implement a disposal program and resolve the issue

of used fuel disposal, garnering public support for new nuclear units will be a difficult challenge.

Need for a Reliable, Competitive Nuclear Fuel Market

Nuclear plants have enjoyed a high degree of reliability with regard to fuel supply, with the vast majority of uranium and enrichment services provided domestically. The nuclear industry has also benefited from a relatively competitive market for fuel and fuel services in recent years, which has kept prices for enrichment services relatively low. This has been important in making nuclear energy competitive with other energy sources because fuel is one of the largest single components in the cost of generating electricity. A fair and open competitive market for enrichment services must be maintained to prevent the possibility of dramatic increases in the cost of nuclear fuel. However, pending anti-dumping and countervailing duty allegations raised by the United States Enrichment Corporation (USEC) threaten to result in a single source of enrichment services in the United States. Should USEC prevail in the pending trade actions, nuclear utilities in the United States anticipate fuel cost increases of between $650 to $1,250 million per year for the industry as a whole.

USEC is also attempting to retain its position as the sole Executive Agent for implementation of the U.S-Russian Highly Enriched Uranium (HEU) Agreement. If USEC is permitted to retain exclusive access to enriched uranium brought into the United States under the HEU Agreement, they will further limit potential competition in the enrichment market. A competitive fuel market is essential to ensuring a reasonably priced fuel supply for nuclear reactors and, consequently for consumers.

Legislative and Regulatory Reforms are Needed

We strongly believe that the safety philosophy embodied in the Reactor Oversight Process should be codified in regulations to further institutionalize this important change. In addition, existing duplicative and inconsistent radiation protection standards between Federal agencies must be resolved and ultimate authority for those standards should rest with the NRC. We also agree with the NRC's recommendations for legislation that would improve the Commission's flexibility in decision-making and reduce unnecessary regulatory burden. However, if prohibitions on foreign ownership are lifted, we feel that doing so should be tied to providing reciprocal rights for U.S. companies to compete overseas.

Stable New Plant Regulatory Framework Needed

The time is right for the next generation of nuclear plants to emerge as an element in the national energy mix. What will it take for new nuclear plants to be built in the United States? The answer to that question has changed in recent years as the nation's electric industry has been restructured. In addition to being safe, reliable, and clean, new plants have to possess an additional characteristic: as merchant plants, they must be economic. New plants must be able to compete with cleaner coal and natural gas technologies, take less time to construct, and require lower initial investments. In today's environment, a new nuclear plant must be relatively small (in terms of generating capacity) so as not to disrupt the economics of the regional power market that the plant is built to serve.

Above all, we need a licensing process that provides predictable outcomes for applicants. Since the last plants were licensed, numerous changes have taken place in the NRC regulations that support licensing of new plants. However, many of these changes have not been tested in actual licensing proceedings. Moreover, the process needs to be able to accommodate new license applications for merchant plants including small, modular designs.

In order to move forward with the implementation of new reactor technologies, additional design and licensing work is required; so are regulatory changes. We must further reduce the uncertainty of the one-step licensing process contained in 10 CFR Part 52. Part 52 contemplates a one-step process to site, design, construct, and operate a new plant. We applaud the goal of a one-step process and believe that such a process is essential. However, we believe that additional work on the process will be necessary, particularly when it comes time to license a gas-cooled reactor.

We need a safety-focused and risk-informed technical licensing framework for new reactors that embodies the NRC's safety philosophy. We also need changes to regulations to make them compatible with applications for so-called "merchant" plants. These changes should include eliminating the need for decommissioning funding assurance and analysis of transmission system stability. Informal hearing procedures should be extended to a wider array of licensing actions while ensuring continued opportunities for public participation. Existing regulations should be reviewed for their potential adverse impact on small, modular designs. NRC fees should be as-

sessed on a "per site" basis rather than by the number of reactors. Minimum licensed operator staffing levels should be addressed.

Price-Anderson Act Must be Renewed

Most importantly, we believe the Price-Anderson Act should be renewed indefinitely. However, treatment of modular reactors under the Price Anderson Act must be clarified to avoid the situation where a 10-module, 1100 megawatt plant faces 10-times the liability of a single-unit 1100 megawatt plant.

Need for Public Funding for First-Time Costs

Some form of cost-sharing between the Department of Energy and the private sector may be needed to efficiently and effectively apply the financial resources needed to cover the first-time costs associated with implementing the one-step licensing process contained in 10 CFR Part 52, the cost of developing an advanced reactor licensing framework to be used by the NRC, and the cost of developing the technical expertise needed by the NRC and its consultants to review a new plant application.

DOE funding support must be focused on both near-and long-term design developments. Forms of potential DOE support could include:

- Design approval support for the industry or the NRC;
- Financial support for demonstration projects for first-of-a-kind/untested processes or technologies;
- Development of training programs on emerging technologies (e.g., gas-cooled reactors) that will better enable industry, political leaders and regulators to understand the new technologies and to render well-informed decisions.

Enhanced Nuclear Research and Development (R&D) Programs

Exelon believes that the Nation is at a critical juncture in securing adequate energy resources for the future. Federal support of nuclear R&D programs that enable continued performance improvements for current nuclear plants and timely siting, design, licensing and construction of new nuclear plants should be high priority for the Congress and the Administration.

Improvements in technology have been a major contributor to the improved safety, unit capacity, reliability and cost performance of current U.S. nuclear units and to electricity consumers. Exelon has realized operational and safety benefits of nuclear R&D in many areas (e.g., predictive maintenance, advanced fuel designs, analytical computer models, digital instrumentation and control upgrades, and probabilistic risk assessment tools).

Further research and development is needed to support new nuclear plants in the areas of new reactor and fuel design, code verification and standards development, establishment of a top-down safety-focused and risk-informed regulatory framework, selected materials research projects and process demonstration projects (i.e., early site permitting).

To support a comprehensive national energy policy, R&D funding should support near-term deployment as well as longer-term advancements in reactor design alternatives. Nuclear R&D funding must also be made available to universities supporting nuclear technology degree programs (engineering, physics, materials, etc.) so that these programs can increase in size. This support for university programs leads to the development of high quality nuclear professionals to sustain the U.S. nuclear infrastructure.

Retain and Attract Top Talent

Nuclear stakeholders must band together to address short and longer-term staffing needs. At Exelon, 69 percent of our nuclear workforce is over 40 with 19 percent over 50. A similar analysis by the NRC of their own workforce demographics yielded more extreme results. We need a viable feeder group of nuclear professionals to operate and maintain our plants. Nuclear industry suppliers and associations will need this talent to preserve the nuclear industry infrastructure. Government agencies such as DOE, NRC, and the national laboratories will need this talent to carry out their respective missions. Universities will need new faculty to conduct research and to educate future generations of nuclear professionals.

In order to retain and attract the top talent, it is imperative to create and sustain a favorable environment for nuclear energy that sends a clear message that nuclear professionals have expanding opportunities with bright futures. We each have a part to play through our support of university programs involving nuclear technologies; through nuclear R&D funding; through achievement of regulatory reform and investment in license renewal and new nuclear technologies. Each of these actions sends a message.

Exelon helped to create and remains active in the DOE/Industry Matching Grant Program for University Nuclear Engineering Departments. This program has had

a major impact in improving the educational infrastructure for supplying nuclear engineers and has allowed the departments to enhance the quality of their programs. In the upcoming fiscal year, the DOE has 23 universities and 37 sponsors vying for funding under the Marching Grant Program. Exelon remains actively involved with nuclear programs at several universities in Illinois, Pennsylvania, and Wisconsin. However, a national program is needed to support a strategic energy policy.

Environmental Policy that Recognizes Nuclear Advantages

The Federal Governmental should treat all energy sources similarly with regard to environmental regulation. Support for environmentally beneficial methods of generation should be based on objective, scientific criteria that accurately measure potential adverse impacts from such generation for all environmental media and resources, taking into account the actual amount of electricity that could be produced. For example, an "environmentally preferable power" certification system could be developed that would recognize nuclear efficiency projects as environmentally preferable. In addition, measures to obtain economic value for nuclear energy's role in avoiding emissions of air pollutants and greenhouse gases, such as emissions allowances or credit for avoided carbon dioxide emissions, should be put in place. Further, any future legislation to implement global warming programs should provide nuclear efficiency improvements with carbon dioxide credits or provide similar recognition of nuclear's valuable role as an emissions-free energy source.

Proper Alignment of NRC Resources

In light of all the changes and challenges that the NRC must manage, proper allocation of resources will be critical to the Commission's success. The stability of the regulatory environment hinges, in part, on the NRC's ability to establish a proper balance and priority between existing reform efforts and new initiatives.

Through a more robust strategic planning process, the NRC has taken steps to keep pace with industry restructuring and to ensure that the Commission can continue to be supportive of our country's growing energy needs. The NRC is updating its blueprint for its transition to a more risk-informed regulatory framework and has recently increased its focus on the licensing of new nuclear plants. Effective implementation of the Reactor Oversight Process and achievement of efficiencies in other areas can enable NRC resources to be realigned to meet the future demands it will face.

Exelon believes that the following areas will require significant NRC attention and resources over the next 5 years:

- Efficient processing of license renewal applications;
- Licensing of generation improvements (e.g., 24-month operating cycles, power rating increases);
- Licensing of new nuclear technologies (e.g., steam generator programs, advanced non-light water reactor designs);
- Licensing of a geologic repository for used nuclear fuel; and
- Further regulatory reforms (e.g., risk-informed regulation, regulatory burden reduction, and further Reactor Oversight Process improvements).

Exelon supports the analysis and redeployment of NRC operations to reflect the need to simultaneously support multiple strategic initiatives while keeping its eye on the ball properly executing its core mission to protect public health and safety.

THE PEBBLE BED MODULAR REACTOR PROJECT

To provide a context for the changes I just described, let me describe Exelon's plans. Exelon Generation has evaluated various technologies and options for future electricity generation and has determined that small, modular nuclear power plants could provide a competitive advantage in the deregulated wholesale power marketplace. These plants could also make a significant contribution to the reduction of greenhouse gases and air pollution usually attributed to electric generation. As a result, we have invested in a joint venture to study the feasibility of an advanced nuclear reactor design called the Pebble Bed Modular Reactor (PBMR). These reactors are small (110–125 megawatts), modular, gas-cooled designs intended for merchant plant installations anywhere in the world. This technology is currently being developed in the Republic of South Africa. We are investigating the technical, licensing, and economic feasibility of building new power plants based on this technology in the United States.

The key advantages of this technology appear to be:

- Increased nuclear safety;
- Minimal environmental impact with no greenhouse gas emissions;
- Low capital and operating costs;

- Stable fuel costs;
- Short construction time; and
- The flexibility to add incremental capacity in regional markets to economically match load growth.

We believe that these advantages are clearly in both our competitive interest and in the national interest.

If the technology is deemed ready for commercialization, and if the economics prove to be competitive against other forms of generation, Exelon and its partners will proceed to build a demonstration plant in South Africa near Cape Town. Construction of that plant will take approximately thirty-six months, followed by a twelve-month testing period.

If Exelon's review of the feasibility study is favorable, we do not intend to wait for the completion of the demonstration plant in South Africa to begin the licensing process to build a number of PBMRs in this country. We will submit a license application for early site permitting in 2002, followed by an application for a combined construction and operating license after the necessary detailed design is completed in South Africa in 2002.

CONCLUSION

In conclusion, as the shortage of electricity supplies in several areas of the country looms large and as our society places an ever-increasing importance on cleaner air, we must find ways to preserve and enhance the nuclear option as a component of the national energy supply. This is an issue of urgent national priority.

Nuclear power has earned the right to be counted among this country's most viable options as a future power source. It has achieved an outstanding safety record and serves as a stable, economic and abundant domestic source of electricity that emits no air pollutants or greenhouse gases associated with fossil-fired plants.

Thank you for giving me the opportunity to share Exelon's perspectives on the state of the nuclear industry, including the importance of a stable and predictable nuclear regulatory environment, and the important role that nuclear power can play.

RESPONSES BY OLIVER D. KINGSLEY, JR., TO ADDITIONAL QUESTIONS FROM SENATOR REID

Question 1. Has the industry completed an economic assessment of this pebble bed type of reactor? What are the projected costs?

Response. The preliminary design of the Pebble Bed Modular Reactor (PBMR) has just been completed in South Africa and the project team is finalizing cost estimates to build the demonstration plant in South Africa. As a project investor, Exelon is now beginning its own internal assessment of the South African cost estimate. The assessment will include a review of the project estimate and an adjustment of the estimate to take into account differences in material and labor costs, productivity rates, and construction techniques. We do not expect to complete our assessment of the PBMR costs for construction and licensing here in the United States until later this year.

Question 2. As you know, the industry—perhaps more than any other industry—has a track record of significantly underestimating the cost of building nuclear power plants by billions of dollars at a time. Why should we believe this design will be any different, considering, in particular, how novel this type of plant is?

Response. The predecessor companies of Exelon experienced first hand the large cost overruns of building nuclear plants. There were several contributors to those cost overruns:

A. Continuing changes in regulatory requirements as a result of the Three Mile Island accident required that plants which were already designed and under construction be redesigned and retrofitted to meet new requirements in order to be licensed. These changes resulted in both additional costs in design and construction work, as well as added costs due to delays.

B. Very high interest rates were prevalent during that period. These high interest charges were added to the cost of the plants and often totaled several billion dollars.

C. The U.S. nuclear industry, unlike the French, did not adopt standard plant designs. That added costs.

We have learned many lessons since that period. All of the regulatory requirements will be defined and known before we start construction as the result of the licensing process we will follow under 10 CFR Part 52. Our exposure to interest rates will be substantially reduced due to the significantly shorter construction

schedule for the PBMR. The industry's improved project management and the modularity of the PBMR design will streamline construction. The U.S. industry will reap the benefit of the South African pilot as well as previous German experience with the reactor type. Finally, these plants will be built and operated as "merchant" plants, not included in any regulated rate base. The risk of cost overruns will be factored into the decision of the investors who would provide the funding to build these plants.

Question 3. A 1998 MIT study of new reactor designs concluded that a 1000-megawatt pebble bed modular reactor would cost approximately $2 billion. With those kinds of costs, do you think a new pebble bed reactor will be able to compete economically without significant government subsidy?

Response. We have not reviewed the MIT study that you reference, but the PBMR design which is being developed and which Exelon is considering is considerably smaller and less expensive than the 1000-megawatt reactor cited in the question. Government subsidization is not being considered. Exelon's decision to proceed as an investor and as a potential operator of the PBMR will be based on our economic analysis that assumes no significant government subsidization.

STATEMENT OF GARY L. JONES, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GENERAL ACCOUNTING OFFICE

Mr. Chairman and members of the subcommittee: We are pleased to be here today to discuss the challenges that the Nuclear Regulatory Commission (NRC) faces as it moves from its traditional regulatory approach, which was largely developed without the benefit of quantitative estimates of risk, to a risk-informed, performance-based approach. Under this approach, NRC will use risk assessment findings, engineering analysis, and performance history to focus attention on the most important safety-related activities, establish objective criteria to evaluate performance, develop measures to assess licensee performance, and focus on results as the primary basis for making regulatory decisions.

NRC is responsible for ensuring that those who use radioactive material—in generating electricity, for experiments in universities, and for such medical uses as treating cancer—do so in a manner that protects the public, the environment, and workers. NRC has issued licenses to 103 operating commercial nuclear power plants and 10 facilities that produce fuel for these plants. In addition, NRC, or the 32 States that have agreements with NRC, regulate almost 21,000 entities that use nuclear materials (nuclear material licensees).[1] In the medical field alone, licensees annually perform an estimated 10 to 12 million diagnostic and therapeutic procedures involving radioactive material.

Our testimony discusses the challenges that NRC faces to (1) implement a risk-informed regulatory approach for commercial nuclear power plants, (2) overcome the inherent difficulties in applying a risk-informed regulatory approach to nuclear material licensees, (3) ensure that the public is confident that safety will be maintained under NRC's risk-informed approach, and (4) hire and retain staff. NRC is aware of the complexities involved and the long-term nature of these types of challenges and has initiated a number of activities to address them. Its performance in addressing them will significantly shape its ability to ensure that commercial nuclear power plants and other licensees operate safely and ultimately that workers, the public, and the environment are adequately protected.

In summary, we found the following:

• NRC's implementation of a risk-informed approach for commercial nuclear power plants is a complex, multiyear undertaking that requires basic changes to the regulations and processes it uses to ensure the safe operation of these plants. NRC faces a number of challenges to develop and implement this new approach. For example, just developing a "roadmap" to guide the agency through this complex process is a challenge. We recommended such a "roadmap" in March 1999. We suggested that a clearly defined strategy that would describe the regulatory activities NRC planned to change to a risk-informed approach, the actions needed to accomplish this transformation, and the schedule and resources needed to make these changes would help guide the regulatory transformation. While NRC developed the Risk-Informed Regulation Implementation Plan to address our recommendation, we believe the plan could be more comprehensive to cover such areas as activities that cut across the agency, resources, performance measures, or how various activities are interrelated.

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[1] Currently, NRC has agreements with 32 States that they, rather than NRC, regulate such entities as universities and hospitals that handle nuclear material.

• NRC needs to overcome a number of inherent difficulties as it seeks to apply a risk-informed regulatory approach to nuclear material licensees. Of most importance, the sheer number of licensees—almost 21,000—and the diversity of activities they conduct—converting uranium, transporting radioactive material, and using radioactive material for industrial, medical, or academic purposes increase the complexity of developing a risk-informed regulatory approach for material licensees. In addition, NRC will be challenged to define its role as an increasing number of States assume responsibility for regulating nuclear material users within their borders. The decisions that NRC ultimately makes on these fronts could have budgetary and other implications for the agency.

• Another challenge for NRC will be to demonstrate that it is meeting one of its performance goals under the Government Performance and Results Act—increasing public confidence in NRC as an effective regulator. This is because NRC has not defined the "public" that it is targeting and does not have a baseline by which to measure the "increase." To address this performance goal, NRC instituted an 18-month pilot effort to use feedback forms at the conclusion of public meetings. The feedback forms will provide information on the extent that the public was aware of the meeting and the clarity, completeness, and thoroughness of the information that NRC provided at the meetings. It is not clear, however, how NRC will use this type of information to demonstrate that public confidence in NRC as a regulator has increased.

• Like other Federal agencies, NRC faces challenges in human capital management, such as replacing a large percentage of its technical staff and senior managers who are eligible to retire. The loss of its staff is compounded by the tight labor market for experienced professionals, the workload projected by the industry to extend the operating licenses of existing plants and transfer the ownership of others, and the declining university enrollment in nuclear engineering studies and other fields related to nuclear safety. NRC has developed a 5-year plan to identify and maintain the core competencies it needs and has identified legislative options, such as allowing the rehire of retired staff without jeopardizing their pension payments, to help resolve its aging staff issue. To assess how existing human capital approaches support an agency's mission, goals, and other organizational needs, we developed a human capital framework, which identified a number of elements and underlying values that are common to high-performing organizations.[2] NRC's 5-year plan generally includes the human capital elements that we suggested.

NRC FACES CHALLENGES TO IMPLEMENT A RISK-INFORMED REGULATORY APPROACH FOR COMMERCIAL NUCLEAR POWER PLANTS

NRC's implementation of a risk-informed, performance-based regulatory approach for commercial nuclear power plants is complex and will require many years to fully implement. It requires basic changes to the regulations and NRC's processes to ensure the safe operation of these plants. NRC faces a number of challenges to develop and to implement this process. For example, because of the complexity of this change, the agency needs a strategy to guide its development and implementation. We recommended such a strategy in March 1999. We suggested that a clearly defined strategy would help guide the regulatory transformation if it described the regulatory activities NRC planned to change to a risk-informed approach, the actions needed to accomplish this transformation, and the schedule and resources needed to make these changes.[3] NRC initially agreed that it needed a comprehensive strategy, but it has not developed one. As one NRC Commissioner said in March 2000, "We really are . . . inventing this as we go along [and] given how much things are changing, it's very hard to plan even 4 months from now, let alone years from now." NRC did develop the Risk-Informed Regulation Implementation Plan, which includes guidelines to identify, set priorities for, and implement risk-informed changes to regulatory processes. The plan also identifies specific tasks and projected milestones.

The Risk-Informed Regulation Implementation Plan is not as comprehensive as it needs to be, because it does not identify performance measures, the items that are critical to achieving its objectives, activities that cut across its major offices, resources, or the relationships among the more than 40 separate activities (25 of which pertain to nuclear plants). For example, risk-informing NRC's regulations will be a formidable task because they are interrelated. Amending one regulation can potentially affect other regulations governing other aspects of nuclear plant oper-

[2] *Human Capital: A Self-Assessment Checklist for Agency Leaders* (AO/OCG–14G, Sept. 2000).
[3] *Nuclear Regulation: Strategy Needed to Regulate Safety Using Information on Risk* (GAO/RCED–99–95, Mar. 19, 1999).

ations. NRC found this to be the case when it identified over 20 regulations that would need to be made consistent as it developed a risk-informed approach for one regulation. NRC expects that its efforts to change its regulations applicable to nuclear power plants to focus more on relative risk will take 5 to 8 years.

NRC has compounded the complexity of moving to a new regulatory approach by deciding that compliance with such an approach will be voluntary. As a result, NRC will be regulating with two different systems—one for those utilities that choose to comply with a risk-informed approach and another for those that choose to stay with the existing regulatory approach. It is not clear how this dual system will be implemented.

One part of the new risk-informed approach that has been implemented is a new safety oversight process for nuclear power plants. It was implemented in April 2000; and since then, NRC's challenge has been to demonstrate that the new approach meets its goal of maintaining the same level of safety as the old approach, while being more predictable and consistent. The nuclear industry, States, public interest groups, and NRC staff have raised questions about various aspects of the process. For example, the industry has expressed concern about some of the performance indicators selected. Some NRC staff are concerned that the process does not track all inspections issues and NRC will not have the information available, should the public later demand accountability from the agency. Furthermore, it is very difficult under the new process to assess those activities that cut across all aspects of plant operations—problem identification and resolution, human performance, and safety conscious work environment. In June 2001, NRC staff expect to report to the Commission on the first year of implementation of the new process and recommend changes, where warranted.

NRC NEEDS TO OVERCOME INHERENT DIFFICULTIES TO APPLY A RISK-INFORMED APPROACH TO NUCLEAR MATERIAL LICENSEES

NRC is facing a number of difficulties inherent in applying a risk-informed regulatory approach for nuclear material licensees. The sheer number of licensees—almost 21,000—and the diversity of the activities they conduct—converting uranium, decommissioning nuclear plants, transporting radioactive materials, and using radioactive material for industrial, medical, or academic purposes—increase the complexity of developing a risk-informed approach that would adequately cover all types of licensees. For example, the diversity of licensees results in varying levels of analytical sophistication; different experience in using risk-informed methods, such as risk assessments and other methods; and uneven knowledge about the analytical methods that would be useful to them. Because material licensees will be using different risk-informed methods, NRC has grouped them by the type of material used and the regulatory requirements for that material. For example, licensees that manufacture casks to store spent reactor fuel could be required to use formal analytical methods, such as a risk assessment. Other licensees, such as those that use nuclear material in industrial and medical applications, would not be expected to conduct risk assessments. In these cases, NRC staff said that they would use other methods to determine those aspects of the licensees' operations that have significant risk, using an approach that considers the hazards (type, form, and quantity of material) and the barriers or physical and administrative controls that prevent or reduce exposure to these hazards.

Another challenge associated with applying a risk-informed approach to material licensees is how NRC will implement a new risk-informed safety and safeguards oversight process for fuel cycle facilities. Unlike commercial nuclear power plants, which have a number of design similarities, most of the 10 facilities that prepare fuel for nuclear reactors perform separate and unique functions. For example, one facility converts uranium to a gas for use in the enrichment process, two facilities enrich or increase the amount of uranium–235 in the gas, and five facilities fabricate the uranium into fuel for commercial nuclear power plants. These facilities possess large quantities of materials that are potentially hazardous (i.e., explosive, radioactive, toxic, and/or combustible) to workers. The facilities' diverse activities makes it particularly challenging for NRC to design a "one-size-fits-all" safety oversight process and to develop indicators and thresholds of performance. In its recently proposed new risk-informed safety oversight process for material licensees, NRC has yet to resolve such issues as the structure of the problem identification, resolution, and corrective action program; the mechanics of the risk-significance determination process; and the regulatory responses that NRC would take when changes in performance occur. NRC had planned to pilot test the new fuel cycle facility safety oversight process in fiscal year 2001, but staff told us that this schedule could slip.

NRC also faces challenges in redefining its role in a changing regulatory environment. As the number of agreement States increases beyond the existing 32, NRC must continue to ensure the adequacy and consistency of the States' programs as well as its own effectiveness and efficiency in overseeing licensees that are not regulated by the agreement States. NRC has been working with the Conference of Radiation Control Program Directors (primarily State officials) and the Organization of Agreement States to address these challenges. However, NRC has yet to address the following questions: (1) Would NRC continue to need staff in all four of its regional offices as the number of agreement States increases?; (2) What are the appropriate number, type, and skills for headquarters staff?; and (3) What should NRC's role be in the future? Later this month, a NRC/State working group expects to provide the Commission with its recommended options for the materials program of the future. NRC wants to be in a position to plan for needed changes because in 2003, it anticipates that 35 States will have agreements with NRC and that the States will oversee more than 85 percent of all material licensees.

NRC FACES CHALLENGES IN DEMONSTRATING INCREASED LEVELS OF PUBLIC CONFIDENCE—ONE OF ITS GOALS UNDER THE GOVERNMENT PERFORMANCE AND RESULTS ACT

Another challenge NRC faces is to demonstrate that it is meeting one of its performance goals under the Government Performance and Results Act—increasing public confidence in NRC as an effective regulator.[4] There are three reasons why this will be difficult. First, to ensure its independence, NRC cannot promote nuclear power, and it must walk a fine line when communicating with the public. Second, NRC has not defined the "public" that it wants to target in achieving this goal. Third, NRC has not established a baseline to measure the "increase" in its performance goal. In March 2000, the Commission rejected a staff proposal to conduct a survey to establish a baseline. Instead, in October 2000, NRC began an 18–month pilot effort to use feedback forms at the conclusion of public meetings. Twice a year, NRC expects to evaluate the information received on the forms to enhance its public outreach efforts. The feedback forms that NRC currently plans to use will provide information on the extent to which the public was aware of the meeting and the clarity, completeness, and thoroughness of the information provided by NRC at the meetings. Over time, the information from the forms may show that the public better understands the issues of concern or interest for a particular plant. It is not clear, however, how this information will show that public confidence in NRC as a regulator has increased. This performance measure is particularly important to bolster public confidence as the industry decides whether to submit a license application for one or more new nuclear power plants. The public has a long history with the traditional regulatory approach and may not fully understand the reasons for implementing a risk-informed approach and the relationship of that approach to maintaining plant safety.

NRC FACES HUMAN CAPITAL DIFFICULTIES

In a highly technical and complex industry, NRC is facing the loss of a significant percentage of its senior managers and technical staff. For example, in fiscal year 2001, about 16 percent of NRC staff are eligible to retire, and by the end of fiscal year 2005, about 33 percent will be eligible. The problem is more acute at the individual office level. For example, within the Office of Nuclear Reactor Regulation, about 42 percent of the technical staff and 77 percent of senior executive service staff are eligible for retirement.[5] During this period of potentially very high attrition, NRC will need to rely on that staff to address the nuclear industry's increasing demands to extend the operating licenses of existing plants and transfer the ownership of others. Likewise, in the Office of Nuclear Regulatory Research, 49 percent of the staff are eligible to retire at the same time that the nuclear industry is considering building new plants. Since that office plays a key role in reviewing any new plants, if that office looses some of its highly skilled, well-recognized research specialists to retirement, NRC will be challenged to make decisions about new plants in a timely way, particularly if the plant is an untested design.

In its fiscal year 2000 performance plan, NRC identified the need to maintain core competencies and staff as an issue that could affect its ability to achieve its perform-

[4] NRC's four performance goals are to maintain safety, increase public confidence, reduce unnecessary regulatory burden, and enhance the effectiveness and efficiency of its activities and decisions.

[5] The Office of Nuclear Reactor Regulation is responsible for ensuring that commercial nuclear power plants operate safely and do not endanger the public or the environment.

ance goals. NRC noted that maintaining the correct balance of knowledge, skills, and abilities is critical to accomplishing its mission and is affected by various factors. These factors include the tight labor market for experienced professionals, the workload as projected by the nuclear industry to transfer and extend the licenses of existing plants, and the declining university enrollment in nuclear engineering studies and other fields related to nuclear safety. In October 2000, NRC's Chairman requested the staff to develop a plan to assess the scientific, engineering, and technical core competencies that NRC needs and propose specific strategies to ensure that the agency maintains that competency. The Chairman noted that maintaining technical competency may be the biggest challenge confronting NRC.

In January 2001, NRC staff provided a suggested action plan for maintaining core competencies to the Commission. The staff proposed to begin the 5-year effort in February 2001 at an estimated cost of $2.4 million, including the costs to purchase software that will be used to identify the knowledge and skills needed by NRC. To assess how existing human capital approaches support an agency's mission, goals, and other organizational needs, we developed a human capital framework, which identified a number of elements and underlying values that are common to high-performing organizations. NRC's 5-year plan appears to generally include the human capital elements that we suggested. In this regard, NRC has taken the initiative and identified options to attract new employees with critical skills, developed training programs to meets its changing needs, and identified legislative options to help resolve its aging staff issue. The options include allowing NRC to rehire retired staff without jeopardizing their pension payments and to provide salaries comparable to those paid in the private sector. In addition, for nuclear reactor and nuclear material safety, NRC expects to implement an intern program in fiscal year 2002 to attract and retain individuals with scientific, engineering, and other technical competencies. It has established a tuition assistance program, relocation bonuses, and other inducements to encourage qualified individuals not only to accept but also to continue their employment with the agency. NRC staff say that the agency is doing the best that it can with the tools available to hire and retain staff. Continued oversight of NRC's multiyear effort is needed to ensure that it is being properly implemented and is effective in achieving its goals.

Mr. Chairman and members of the subcommittee, this concludes our statement. We would be pleased to respond to any questions you may have.

STATEMENT OF STEVEN M. FETTER, MANAGING DIRECTOR, GLOBAL POWER GROUP
FITCH, INC.

I appreciate the opportunity to return to the Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety to continue discussions about the appropriate role for the Nuclear Regulatory Commission (NRC) in the evolving utility competitive environment. Fitch is the international credit rating agency that resulted from mergers among three rating agencies: the New York-based Fitch Investors Service, the London-based IBCA Limited, and the Chicago-based Duff & Phelps. I will speak from the perspective of a member of the financial community as well as former Chairman of the Michigan Public Service Commission. I also note that I am not a nuclear engineering or nuclear physics expert, and in this regard I am representative of the large majority of investors and financial analysts who play some role in assessing the nuclear industry.

The manner in which the NRC carries out its responsibilities during the electric industry's transition to competition will have a profound impact as to the role nuclear power will play within the restructured utility environment. As I have testified before, the NRC is at the center of investors' perceptions of the financial risks facing the U.S. nuclear industry. In evaluating utilities that operate nuclear plants, debt and equity investors study closely the processes and actions of the NRC. To the extent that these regulatory responsibilities are carried out in a consistent and predictable manner, investors find comfort with the outlook for both individual nuclear utilities and the nuclear industry as a whole.

I am extremely encouraged by the actions of the NRC beginning soon after the July 1998 NRC oversight hearing. Responding to this subcommittee's encouragement and under the leadership of NRC Chairmen Shirley Ann Jackson and later Richard Meserve, the NRC has welcomed interested stakeholders into the formulation and implementation of a reactor oversight process that focuses on objective assessment of safety-related factors. Using clearer standards based upon individual plant characteristics, the agency has been able to direct its attention for maximum impact. Moreover, leaving the somewhat nebulous Systematic Assessment of Licensee Performance (SALP) and Watch List behind, the NRC has increased the

transparency of its processes to both the industry and the public through an NRC website that provides more information than has ever been available before.

The NRC's initial experience with the processes of transferring and renewing nuclear licenses bodes well for the future. The agency set optimistic targets for both of these activities and then easily beat their deadlines. If the NRC can continue this positive track record when license renewal applications grow from a handful into double digits, and further streamline its regulatory activities while not compromising safety, it should secure the more than 20 percent of the Nation's power supply that comes from nuclear energy. Down the road, it is likely that the NRC will face even more important licensing issues involving new nuclear plants, both pre-and-post construction. It appears that the NRC will attempt to carry out its responsibilities in this regard with the same level of sensitivity that it has shown on reactor oversight and existing license transfers and renewals. Testifying before the Senate Energy and Natural Resources Committee last week, NRC Chairman Meserve concluded:

> The Commission has long been, and will continue to be, active in concentrating its staffs' efforts on ensuring the adequate protection of public health and safety, the common defense and security, and the environment in the application of nuclear technology for civilian use. Those statutory mandates notwithstanding, the Commission is mindful of the need to: (1) Reduce unnecessary burdens, so as not to inappropriately inhibit any renewed interest in nuclear power; (2) Maintain open communications with all of its stakeholders, in order to seek to ensure the full, fair, and timely consideration of issues that are brought to our attention; and (3) Continue to encourage its highly qualified staff to strive for increased efficiency and effectiveness, both internally and in our dealings with all of the Commission's stakeholders.

Chairman Meserve also called on the Congress to extend the Price-Anderson Act, which establishes a framework that provides assurance that adequate funds are available in the event of a nuclear accident, beyond its August 1, 2002 expiration. Without the framework provided by the Act, private sector investment in nuclear power would be severely chilled due to the potential risk of large liabilities. With NRC leadership on record with messages like these, investors will be more likely to support an expanded role for nuclear power.

For example, consider the significant change in perception since the time of the first in this series of oversight hearings. In 1998, the two most frequent topics upon which I was invited to speak were "Is there a place for nuclear power in the evolving competitive environment?" and "California's success in the evolution to electric restructuring." Today, the concerns are the same but you can juxtapose the words "nuclear power" and "California." I have more confidence that nuclear power will be an integral part of the restructured environment than I am that California will soon remedy the flaws that it built into the State's competitive framework.

Consistent with this bullish stance on the future of nuclear power is the action Fitch took last week in rating Exelon Generation Company LLC (ExGen), a newly formed non-regulated subsidiary of Exelon, the holding company created by the merger of Unicom Corporation and PECO Energy Company (see Attachment One: Fitch Press Release dated May 2, 2001). Fitch assigned an implied "BBB+" rating to the senior unsecured debt obligations of ExGen—a respectable investment-grade rating—notwithstanding the company's ownership and operation of 19 nuclear plants at 11 locations.

Fitch found that ExGen's significant nuclear exposure is mitigated by the diversity of the nuclear asset fleet, an excellent record as a nuclear operator, the sourcing and marketing capability of its trading operations, and adequate liquidity. Far from representing a financial drag on a utility entering the competitive landscape, ExGen's well-conceived emphasis on nuclear energy, accompanied as it is by excellent plant condition, strong operational performance, and adequate decommissioning funding, seems to offer a competitive advantage.

Similarly, Fitch rated PSEG Power LLC's (PSEG Power) initial offering of $1.8 billion of senior unsecured debt "BBB+," despite its primarily merchant character after July 2002 and significant reliance on nuclear generation (63 percent in 2001 declining to 43 percent in 2005) (see Attachment Two: Fitch Press Release dated March 26, 2001). PSEG Power's rating was favorably impacted by its location and participation in the Pennsylvania-New Jersey-Maryland (PJM) power grid, which facilitates a large and liquid energy market.

There is much to support an expanding role for nuclear generation some time in the future. Nuclear's air quality benefits cannot be matched by fossil-fueled plants and nuclear fuel is not subject to the degree of volatility we have recently seen in natural gas prices in the western half of the United States. That all said, the ele-

phant in the corner is disposal of spent nuclear fuel. Progress on choosing and developing a permanent site for the disposal of spent fuel is a necessity. Before we see progress on planning for the construction of a new generation of nuclear plants, the waste issue must be resolved. Any delay in achieving this goal likewise delays the ability of the nuclear industry to assist in the country's future electricity needs.

ATTACHMENT ONE: FITCH PRESS RELEASE ON EXELON GENERATION COMPANY LLC

FITCH UPGRADES EXELON & PECO; RATES EXELON GENERATION CO. "BBB+"

Fitch today upgraded the senior unsecured debt of Exelon Corporation (Exelon) to "BBB+" from "BBB" and upgraded the senior secured debt of PECO Energy Company (PECO) to "A" from "A-." Simultaneously, Fitch assigned an implied "BBB+" rating to the senior unsecured debt obligations of Exelon Generation Company LLC (ExGen), a newly formed non-regulated subsidiary. Fitch also affirmed the senior secured rating of Commonwealth Edison Company (ComEd) at "A-." The Rating Outlook for Exelon and all of its subsidiaries is Stable. A complete recap of Fitch's rating action with respect to Exelon and its subsidiaries is shown below.

The upgrade of Exelon primarily reflects the holding company's strong consolidated credit measures, the predictable cash-flow of its regulated distribution subsidiaries (PECO and ComEd), the availability of unrestricted dividend payments from its three core operating subsidiaries, the scale and diversity of its generation subsidiary (ExGen) and the contractual commitments between ExGen and the regulated distribution companies. The contractual arrangements between the subsidiaries substantially reduce consolidated business risk. The credit profile of Exelon and its subsidiaries is further strengthened by management's commitment to issue equity as may be needed to maintain a capital structure that is appropriate for the credit ratings. The company's significant nuclear exposure is mitigated by the diversity of the nuclear asset fleet, an excellent record as a nuclear operator, the sourcing and marketing capability of its trading operations and adequate liquidity.

The ratings upgrade of PECO and the affirmation of ComEd reflect the strength of the companies' actual and projected financial results and the absence of commodity price exposure. Both entities have entered into full requirements supply contracts with ExGen covering each company's provider of last resort (PLR) obligation. PECO's PLR obligation extends through 2010 and ComEd's through 2004. Both utility subsidiaries have implemented restructuring plans that resolved stranded cost concerns and insure a steady revenue stream from the regulated transmission and distribution businesses.

The "BBB+" rating of ExGen's senior unsecured obligations recognizes the scale and geographic diversity of the generation portfolio, the all-requirements sales agreements with PECO and ComEd that assure a predictable revenue stream for the term of the contracts, modest leverage and strong financial projections. Moreover, ExGen has a very competitive cost structure that is well positioned to produce consistent cash-flow when operating on a merchant basis. Since a majority of the portfolio is base load nuclear capacity, it is expected to achieve a high level of dispatch in most price scenarios. The significant nuclear exposure is mitigated by the diversity of the portfolio, with 19 units at 11 nuclear stations. According to the independent engineer Sargent and Lundy LLC (S&L), the nuclear units are in excellent condition and improving in operational performance. Decommissioning funding provisions are adequate and long-term waste fuel storage at each site has been addressed, either through the inclusion of dry cask storage costs or re-racking of the spent fuel pools.

The power marketing and trading activity, Power Team, is closely linked to, and supports, the generation assets. The Power Team markets physical capacity and does not act as a market maker, thereby limiting its risk exposure. By maintaining a net positive supply position, ExGen is able to limit operational risk. Power Team also benefits from a sizable amount of contractual transmission capacity. Risk management policies appear to be prudent.

ExGen's capital structure begins with a modest 35 percent debt ratio, growing to about 43 percent in 2003 (excluding non-recourse project finance debt). Due to the low amount of financial leverage, ExGen is expected to produce interest coverages (after capital expenditures) of 4×6 times (×) in the next 10 years and over 2.75 × in a stress scenario.

Exelon is the holding company created by the merger of Unicom Corporation and PECO. With the completion of the merger in October 2000, PECO and ComEd became distribution companies only; all power generating assets and wholesale power

marketing operations of PECO and ComEd, along with other generating assets owned by Exelon, were transferred to the newly created ExGen.

The following summarizes the rating actions announced today for Exelon and its subsidiaries:

Exelon Corp.:
- Senior Unsecured Debt (implied) to "BBB+" from "BBB";
- Commercial Paper affirmed at "F2."

PECO Energy Company:
- First Mortgage Bonds to "A" from "A-";
- Senior Unsecured to "A-" from "BBB+";
- Pollution Control Revenue Bonds (non-collateralized) to "A-" from "BBB+";
- Preferred Stock to "BBB+" from "BBB";
- Trust Preferred Stock to "BBB+" from "BBB";
- Commercial Paper to "F1" from "F2."

Commonwealth Edison Company
- First Mortgage Bonds affirmed at "A-";
- Senior Unsecured affirmed at "BBB+";
- Pollution Control Revenue Bonds (noncollateralized) affirmed at "BBB+";
- Preferred Stock affirmed at "BBB";
- Trust Preferred Stock affirmed at "BBB";
- Commercial Paper affirmed at "F2."

Exelon Generation Company:
- Senior Unsecured Debt (implied) assigned new rating of "BBB+".

ATTACHMENT TWO: FITCH PRESS RELEASE ON PSEG POWER LLC

FITCH EXPECTS TO RATE PSEG POWER LLC SR UNSECURED DEBT "BBB+"

Fitch expects to rate PSEG Power LLC's (Power) initial offering of $1.6 billion of senior unsecured debt "BBB+." Power is a wholly owned subsidiary of Public Service Enterprise Group (PSEG) and the parent holding company of PSEG's portfolio of non-regulated domestic electric generation assets and energy trading organization. Power was formed in July 1999 to acquire, own and operate the electric generation assets of Public Service Electric and Gas Company (PSE&G). The Rating Outlook is Stable.

The rating reflects the scale and diversity of PSEG Power's generating portfolio, strong projected financial measures, competitive cost structure, and the sound sourcing and marketing capability of its energy trading and marketing organization. The company's overall risk profile also benefits from its location and participation in the Pennsylvania-New Jersey-Maryland (PJM) power grid, which is a large and liquid energy market located in the populous Mid-Atlantic region of the eastern U.S.

The credit rating also takes into consideration Power's primarily merchant character after July 2002 when the company's off-take contract with PSE&G expires, the potential for excessive new plant construction, evolving environmental regulations, and nuclear operating risk. The merchant risk is mitigated by the likelihood that Power will enter into a new power contract with PSE&G and/or other PJM utilities after expiration of its existing contract. Because of the scale and location of Power's assets, the company is well positioned to serve PSE&G's retail load, either directly or indirectly, well beyond the current contract period. Market competition could become more of a concern as Power expands its merchant facilities outside of PJM.

The high percentage of net cash-flow derived from coal and nuclear units makes Power's fixed charge coverage sensitive to low gas prices. Conversely, coverage ratios benefit from high gas prices. Future cash-flows also are sensitive to excessive new plant construction. The capacity over build stress case, produced the lowest fixed charge coverage, falling below 2.5 times (×) in 2001, but still averaged a relatively healthy 4× over the 10 year forecast period. Combining the over build case with a 10 percent increase in operating and maintenance expenses reduced the fixed charge coverage to a below 2× in 2001 and an average of 3.5× over the forecast period.

Power is pursuing a regional generation strategy focussed on the super-region of PJM, New England, East Central Area Coordination Agreement (ECAR), Virginia/Carolina and New York. Currently, 97 percent of Power's capacity is located in PJM, consisting of the formerly jurisdictional assets of PSE&G. The assets were transferred to Power in August 2000 in exchange for a $2.8 billion note. Power also owns a generating facility in New York (380 MW), is developing additional projects in ECAR and PJM and eventually plans to expand its New York facility.

The majority of Power's revenue will be derived from supplying PSE&G's provider of last resort (PLR) load. A full requirements contract extends to July 31, 2002. Thereafter, Power's goal is to bid for 75 percent of the PLR load or enter into other contractual arrangements.

Facilities under construction or in advanced development total about 4,200 MW, including 1,854 MW in PJM, 2,000 MW in ECAR and 350 MW in New York. All the new facilities are natural gas fired simple cycle or combined cycle units and will increase the diversity of Power's generation mix and mode of operation.

In 2001, the generation mix is projected at 63 percent nuclear, 31 percent coal, 6 percent gas/oil and 1 percent pumped storage. By 2005, gas accounts for 38 percent of output, nuclear 43 percent, and coal 19 percent. Based on output, 93 percent of generation is currently base load, 3 percent intermediate and 3 percent peaking. The mode of operation changes in 2005 to 62 percent base load, 35 percent intermediate and 3 percent peaking.

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